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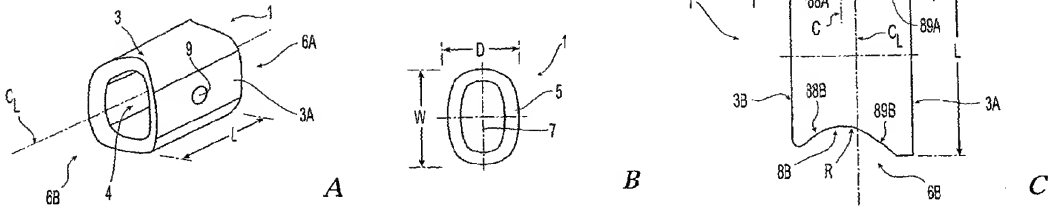

(57) Abstract: Implants (40, 62) for maintaining a distance between cut spinal bones (71, 72) are disclosed. The implants (40, 62) are made of metal, polymer or bone allograft, and have ends (46A, 46B, 63A, 63B) angled with respect to each other to conform to the cut bone ends (71, 72). The implants (1, 62) have hollow regions (49, 70) for packing osteogenic material. The implant ends (46A, 46B, 63A, 63B) have surface projections (56) to reduce slippage. Implants made of bone allograft also have ends made of demineralized bone to speed fusion between spine (71, 72) and implant (40, 62). Methods of using the implants are also disclosed.

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BILATERAL LAMINOPLASTY IMPLANTS

TECHNICAL FIELD

The present invention relates to a medical implant and method, and, more particularly, to an improved surgical implant and method for expanding the spinal canal to eliminate pressure on the spinal cord caused by an impinging vertebral bone.

BACKGROUND OF THE INVENTION

Various medical conditions may result in a reduction of the area within the vertebrae available for the spinal cord. Spinal stenosis is one such condition involving the narrowing of the canal in the center of the spine through which the spinal cord and nerve roots run. Spinal stenosis may result when the ligaments of the spine thicken and calcify (harden from deposits of calcium salts), or when bones and joints enlarge, and osteophytes (bone spurs) form. A herniated (bulging) disk may also place pressure on the spinal cord or nerve root. Furthermore, diseased bone or tumors may result in an ingrowth into the spinal cord area. This decreases the space (neural foramen) available for nerve roots leaving the spinal cord.

Two surgical methods currently exist to create additional room in the spinal canal. The first is called a laminectomy, and involves removal of the lamina (roof) of one or more vertebrae. A limitation of the laminectomy procedure is that it involves removal of the supporting structures at the back of the vertebrae which align the spinal column. The result may be that a patient suffers some postural deformity. To prevent such postural problems, a graft may be installed between the ends of the removed bone to span the void and reinstate the necessary support. The second procedure is called a laminoplasty, in which the targeted vertebra is cut, spread apart and a graft is inserted to permanently enlarge the space. Unlike the laminectomy, typically no bone material is excised during the laminoplasty procedure. Two different laminoplasty procedures are currently used. The first is called the unilateral or "open door" laminoplasty in which one side (lamina) of the vertebra is cut all the way through, while the other side is cut only half way to create a hinge. The vertebral element is then rotated about the hinge, and the graft is inserted into the opening, increasing the opening of the spinal canal. The second

procedure is called the bilateral or "French door" laminoplasty in which the midline of the vertebra (spinous process) is cut all the way through, and the lamina are cut half way through, creating two hinges. The vertebral element is then opened at the bisected spinous process, and a graft inserted into the opening, again increasing the opening of the spinal canal.

Various materials may be used for the grafts installed during laminoplasty procedures. U.S. Patent Nos. 6,080,157 to Cathro et al. and U.S. Patent No. 5,980,572 to Kim et al. disclose the use of titanium, ceramic and nylon inserts. Further, using allografts taken from long bones such as the femur, humerus, tibia and fibula, for spinal fusion procedures is known, as disclosed by U.S. Patent No. 5,728,159 to Stroever et al. Allografts, as such bone grafts are called, are removed from a donor and processed using known techniques to preserve the allograft until implantation. Allografts have mechanical properties which are similar to the mechanical properties of vertebrae even after processing. The benefit of such property matching is that it prevents stress shielding that occurs with metallic implants. Allografts, unlike magnetic metals, are also compatible with magnetic resonance imaging (MRI) procedures, allowing more accurate ascertainment of fusion. Furthermore, allografts are naturally osteogenic providing excellent long term fusion with the patient's own bone.

Several different spacer designs have been used in laminoplasty procedures to the present. For example, the Cathro patent discloses a metal, nylon or teflon spacer for use in a unilateral laminoplasty procedure. The Cathro spacer is a rectangular plate having shouldered edges which engage the ends of the cut lamina, and is held in place by a spring mechanism. The difficulty with the Cathro spacer is that its operation relies on the continued satisfactory operation of the installed spring. Further, the Cathro device provides little available area for the packing of fusion enhancing (*i.e.* osteogenic) material. The Kim patent discloses a spacer for use in a bilateral laminoplasty procedure. The Kim spacer consists of inner and outer trapezoidal segments joined together by a rectangular segment. The tapered surface of the inner trapezoidal segment is designed to conform to the inner surface of the split spinous process halves, while the taper of the outer segment is designed to assume the shape of the removed spinous process tip. The Kim spacer seats on the resulting flat surface of bone. Like the Cathro device, the Kim device provides little area in which to pack osteogenic material to facilitate bone-implant fusion.

Neither the Cathro nor Kim device use allograft as a spacer material, which may result in reduced propensity for fusion and the possibility for stress shielding.

Accordingly, there is a need in the art to provide implants and methods for both laminectomy and unilateral and bilateral laminoplasty procedures, which provide excellent dimensional, strength and retention capability, which enhance fusion with the patient's own bone, which are easy to select, fit and install and which provide excellent compatability with post-operative imaging (MRI).

SUMMARY OF THE INVENTION

The present invention provides implants for use in the spinal column. In one embodiment, the implants have a body portion having a length and configured to be insertable between first and second bone segments. The body has have an outer surface, and an inner surface defining a substantially hollow portion. The implants further have an inner side region having an inner side length, an outer side region having an outer side length, and first and second ends which communicate with the hollow portion. The first and second ends may comprise bone engaging portions. At least one of the bone engaging portions may comprise surface projections to reduce slippage between the bone engaging faces and the respective bone segment. The bone engaging portions may also be angled with respect to each other.

The implant inner side region comprises an angle with each of the bone engaging surfaces, and this angle may range from 50 to 70 degrees. Further, the inner side length of the implant may range from 6 to 10 millimeters. The perimeter of the outer surface of the implant may comprise a substantially geometric shape such as an ellipse or circle. An implant outer surface perimeter comprising an ellipse may have a width ranging from 10 to 11.5 millimeters (mm) and a depth ranging from 6.5 to 7.5 mm.

The implant may have bone engaging surfaces comprising surface projections to reduce slippage between the bone engaging portions and the respective bone segments. These surface projections may comprise saw tooth ridges, or they may be individual pyramidal teeth.

The implant bone engaging portions may comprise channels configured to accept the arms of a pair of distractor pliers. The implant body may have at least one hollow suture attachment portion to enable a surgeon to secure the implant to at least one of the first and second bone segments. The implant may be formed of a biocompatable metal or polymer, or bone allograft material. Where the implant is an allograft, at least one of the bone engaging portions may be comprised of partially, substantially, or fully demineralized bone. The inner surface of the allograft implant may be defined by the intermedullary canal, or the inner surface may be configured so that the volume of the hollow portion is greater than the intermedullary canal.

In a different embodiment, the implant has a body portion formed of bone allograft and have an inner side region comprising an inner side length and configured to be insertable between first and second bone segments. The body may also have first and second ends, where at least one of the ends comprises a bone engaging portion to engage at least one of the bone segments. Either one or both bone segments may be comprised of a partially, substantially, or fully demineralized bone. The implant body portion may further have a wall with an outer surface, and an inner surface defining a substantially hollow portion, where the hollow portion is in communication with the first and second ends. The hollow portion may be defined by the intermedullary canal of the donor bone, or the inner surface may be configured so that the volume of the hollow portion is greater than the intermedullary canal of the donor bone. At least one of the first and second bone engaging portions may have surface projections to retain the implant between the bone segments. The surface projections may be saw tooth ridges or individual pyramidal teeth.

The implant inner side region forms an angle between each of the bone engaging portions, and this angle may range from 50 to 70 degrees. The inner side length may range from 6 to 10 mm.

In a further embodiment, an implant for use in the spinal column has a body portion formed of allograft bone material having an inner side region with an inner side length, and configured to be insertable between first and second segments of spine. The body may have first and second ends, where at least one end has a bone engaging portion to engage at least one of the bone segments. The bone

engaging portion further comprises an outer shell portion comprised of cortical bone substantially surrounding a center region comprised of cancellous bone. The implant may have surface projections on at least one of the bone engaging portions to reduce slippage between the bone engaging portions and the respective bone segment. These surface projections may be saw tooth ridges, or they may be individual pyramidal teeth. At least one of the bone engagement portions may comprised of partially, substantially, or fully demineralized bone.

The implant inner side region forms an angle with each of the bone engagement portions, and this angle may range from 50-70 degrees. The inner side length may range from 6 to 10 mm. The implant width may range from 10 to 11.5 mm and the implant depth may range from 6.5 to 7.5 mm.

A further implant for use in the spinal column is provided, having first and second plates connected by an intermediate portion whose thickness is smaller than the height of the first and second plates. The plates each have a bone engaging portion for engaging the first and second bone segments produced during a laminoplasty. The first and second bone engaging portions are angled with respect to each other. The implant is configured to be insertable between first and second bone segments produced during a laminoplasty procedure. The implant may be configured so that the first and second plates and the intermediate portion form a substantially U-shape. The implant my be comprised of a biocompatable metal or polymer, or cortical bone allograft material. Where the implant is comprised of allograft material, at least one of the bone engaging portions may be comprised of partially, substantially, or fully demineralized bone.

The implant bone engaging portions may have surface projections to reduce slippage between the bone engaging portions and the bone ends. The surface projections may be saw tooth ridges or individual pyramidal teeth.

A method for providing a desired space in the spinal canal is also provided, comprising the steps of: cutting at least one segment of a vertebra all the way through to produce first and second cut bone ends; cutting at least one lamina partially to create a hinge; providing an implant having a body portion comprising a length and a longitudinal axis, the body portion having first and second ends and the first and second ends comprising bone engaging portions, where the implant is

formed of a bone allograft material, and at least one of the bone engaging portions is comprised of partially, substantially, or fully demineralized bone; separating the first and second cut bone ends a sufficient distance to accept the implant; positioning the implant between the first and second cut bone ends; and contacting at least a portion of each of the first and second cut bone ends with the bone engaging portions. In an additional embodiment the step of cutting may comprise bisecting a spinous process. In yet a further embodiment, the method may further include the step of cutting a second lamina of the vertebra partially to create a second hinge.

A method for providing a desired distance between first and second cut bone ends of the spine is also provided, comprising the steps of: cutting at least one segment of a vertebra to produce first and second cut bone ends; providing an implant having a body portion formed of bone allograft material with first and second ends; the first and second ends having bone engaging portions, the bone engaging portions each having an outer shell portion and a central region, the outer shell portion substantially surrounding the central region, wherein the outer shell portion is cortical bone and the center region is cancellous bone; separating the bone ends enough to accept the implant; placing the implant between the bone ends; and positioning the implant so as to contact at least a portion of each of the first and second cut bone ends with the bone engaging portions. In an additional embodiment, the method may also include the step of providing an implant having bone engaging portions comprising surface projections to reduce slippage between the bone engaging portions and the bone ends. These surface projections may comprise saw tooth ridges or they may comprise individual pyramidal teeth. In yet another embodiment, the step of cutting comprises bisecting the spinous process. In an additional embodiment, the cutting step may further comprise partially cutting both laminae adjacent to the spinous process.

BRIEF DESCRIPTION OF THE DRAWINGS

The features and advantages of the implant and method of use will become more readily apparent from the following detailed description of the invention in which like elements are labeled similarly and in which:

FIGS. 1A, 1B and 1C are perspective, end and top views of the first embodiment of the implant, for use in a unilateral laminoplasty procedure;

FIGS. 2A and 2B are side and top views of the implant of FIG. 1 installed between the cut lamina segments of a vertebra during a unilateral laminoplasty procedure;

FIGS. 3A and 3B are a perspective view of a retaining plate of the present invention, and a side view of two such retaining plates installed over the implants of FIGS. 2A and 2B;

FIGS. 4A and 4B are perspective and side views of a second embodiment of the implant, a unilateral implant incorporating demineralized bone flaps;

FIGS. 5A, 5B and 5C are perspective, side and end views of a third embodiment of the implant, for use in a bilateral laminoplasty procedure;

FIGS. 6A and 6B are side and section views of the implant of FIG. 5 showing the incorporation of a channel to accept the corresponding arms of a set of distractor pliers used to install the implant;

FIG. 7 is a detail view of the end of the implant of FIG. 5B showing a preferred embodiment of the surface projections used to facilitate retention of the implant between cut spinous process segments.

FIGS. 8A, 8B and 8C are perspective, end and side views of a fourth embodiment of the implant, for use in a bilateral laminoplasty procedure;

FIG. 9A and 9B are front and top views of the implants of FIGS. 7 and 8 installed between the cut spinous process segments of a vertebra during a bilateral laminoplasty procedure;

FIGS. 10A, 10B and 10C are perspective, end and top views of a fifth embodiment of the implant, for use in a unilateral laminoplasty procedure;

FIGS. 11A, 11B and 11C are top, side and end views of a sixth embodiment of the implant, for use in a unilateral laminoplasty procedure; and

FIGS. 12A and 12B are perspective views of seventh and eighth embodiments of the implant, for use in unilateral laminoplasty procedures.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Preferred embodiments, features and aspects of an implant adapted to be used in unilateral and bilateral laminoplasty procedures are described, in which a portion of a targeted vertebra is cut, the space available for the spinal cord and

associated nerves is expanded, and an implant is installed between the cut segments of bone.

Referring more particularly to the drawings, FIGS. 1A, 1B and 1C show an implant for use in a unilateral or "open door" laminoplasty. The implant 1 has a longitudinal axis "CL," a length "L," a wall 5 defining an outside surface 3 and an inside surface 4, and first and second ends 6A, 6B. Inside surface 4 communicates with first and second ends 6A, 6B to define a hollow central region 7 of the implant. Outside surface 3 has an outer side region 3A and an inner side region 3B such that when the implant is installed between cut segments of lamina, outer side region 3A faces outward away from the spinal canal, while inner side region 3B faces inward toward the spinal canal. The implant 1 further has a depth "D" which is the distance between outer side region 3A and inner side region 3B. Implant 1 also has a width "W" which is the distance between opposing outer surfaces 3 measured along a drawn line perpendicular to a line defining the depth "D." Length "L" preferably should be between about 11.5 millimeters (mm) to about 15.5 mm; depth "D" preferably should be between about 5.5 mm to about 6.5 mm; and width "W" preferably should be between about 8.0 mm to about 9.5 mm.

The shape and size of outside surface 3 is not critical and, therefore, any implant configuration can be used preferably so long as the first and second ends 6A, 6B provide sufficient contact area with the lamina ends, and the implant 1 does not interfere with other anatomy, and does not intrude on the spinal cord space. In a preferred embodiment, however, the outside surface 3 is configured such that the shape of the implant, when viewed from the end, displays the form of a substantially geometric shape (e.g. ellipse, oval, circle, etc.). In this embodiment the exterior dimensions of the implant also approximate those of the outside surface of the cut lamina segments between which the implant is installed. Although implants having cross sections of greater or lesser proportion than the lamina to which they attach will function properly, for aesthetic purposes and in an attempt to minimize the amount of material introduced into a patient's body, the outer surface of the implant should preferably not extend beyond the outer surface of the adjoining bone.

In a further embodiment, the inside surface 4 of the implant 1 may be machined so that the hollow central region 7 approximates the configuration and

geometry of the implant exterior (*i.e.* form an ellipse or oval shape). The hollow central region may be designed to be packed with osteogenic material such as bone chips, etc. to facilitate fusion of the implant with the patient's lamina. Preferably, the central region may be as large as possible to enhance fusion of the implant to the patient's lamina. The thickness of wall 45 preferably should be between about 1.00 to about 1.50 mm; more preferably about 1.25 mm. Preferably the thickness of wall 5 should not be less than about 1.0 mm to ensure the implant retains sufficient strength to withstand the stresses imparted on the spine.

The implant 1 may be fabricated from a biocompatable metal (*e.g.* stainless steel, or titanium, etc.) or polymer, or from allograft material preferably taken from a long bone (*e.g.* femur, tibia, fibula, humerus). Where the implant is an allograft, the inside surface 4 and hollow central region 7 may be defined by the intermedullary canal of the donor bone. The hollow center may be left as such, or the inner surface 4 may be machined, as with other implant materials, to maximize the space available for packing with osteogenic material. Again, the thickness of the implant wall 5, preferably is not reduced to less than about 1.00 mm.

During the unilateral laminoplasty procedure, the targeted lamina is cut in half and the segment attached to the spinous process is rotated or swung out to increase the area available for the spinal cord and associated nerves. Subsequent to this rotation, the lamina segments no longer reside along the same axis, but instead the ends are disposed at an angle with respect to each other. Implant 1 is substantially straight along its length, and so to accommodate this angular displacement of the lamina, first and second ends 6A, 6B incorporate arcuate cutouts 8A, 8B to grasp and retain the cut lamina segments. Viewed from the top of the implant (FIG. 1C), these arcuate cutouts 8A, 8B are generally concave and may be circular in shape, or they may consist of a cutout spanning an obtuse angle and converging to a small radius at the crotch of the first and second ends 6A, 6B. Arcuate cutouts 8A, 8B have a centerline 1a which runs parallel to the longitudinal axis of the implant 1. The centerline 1a of the arcuate cutouts may be coexistent with the longitudinal axis of the implant 1, or it may be offset with respect to that axis to further improve retention of the cut and displaced lamina ends. In a further embodiment, the centerlines 1a of the arcuate cutouts may each be offset on an opposite side of the implant centerline to facilitate retention of the implant in cases where the angle between the cut and spread lamina is more severe, such as when

the surgeon spreads the lamina segments as wide as possible to provide maximum additional space for the spinal cord and associated nerves.

In the preferred embodiment, shown in FIG. 1C, each arcuate cutout 8A, 8B comprises first angled faces 88A, 89A and second angled faces 88B, 89B, respectively, which meet at crotch "C" to form a face angle "A." Preferably, face angle A is about 100 degrees. Crotch radius "R," comprises the transition between the first and second angled faces. Crotch radius "R" is preferably about 2 mm. Each arcuate cutout further comprises first and second face depths "F1" and "F2." The first and second face depths are a measure of the depth of the crotch relative to the inner side region 3B and outer side region 3A of the implant, and will be different lengths whenever the centerline 1a of the arcuate cutout is offset from the centerline "CL" of the implant 1. Preferably first face depth "F1" is about 1.25 mm, and second face depth "F2" is about 1.5 mm. Each arcuate cutout 8A, 8B also has a centerline offset "d," which is the degree to which the arcuate cutout 8A, 8B is shifted from the centerline "CL" of the implant 1. Preferably, the centerline offset "d" is from about 0 to 2.5 mm toward the inner side region 3B of implant 1. The face depth "F1" of the first and 6A of the implant 1 may be the same or different than the face depth "F1" of the second end 6B. Likewise, the face depth "F2" of the first end 6A may be the same or different than the face depth "F1" of the second end 6A.

In a further embodiment of the implant comprising allograft material, first and second ends 8A, 8B may comprise regions of demineralized cortical bone to further facilitate fusion of the implant to the lamina. Preferably the demineralized bone portion comprises the entire surface of each first and second end 6A, 6B of the implant 1. Preferably, the depth of the demineralized portion will be up to about 2 mm.

The implants further may incorporate at least one suture hole 9 in the implant wall 5 to allow the surgeon the option of suturing the implant to the cut lamina ends. These suture holes 9 may vary in number and size, with the only limitation being that they should not be so large or numerous as to compromise the strength or integrity of the implant.

FIGS. 2A and 2B are side and top views of the implant of FIG. 1 installed in a patient between the cut lamina ends in a unilateral laminoplasty

procedure. In FIG. 2A two different sized implants 1 are installed on the cut lamina segments 10 of adjacent vertebrae, to illustrate application of the implant design to bones of different size. FIG. 2B shows the interaction between the implant and the cut vertebra segments 10.

The design of the bone engaging ends 6A, 6B of the implants 1 are sufficient to ensure retention of the implants 1 between the cut ends of lamina 10. Some surgeons, however, desire an additional measure of assurance that the implants 1 will not loosen or otherwise be expelled from between the lamina ends 10. The implant, therefore, provides for the optional installation of a plate 12 to be secured over an installed implant in a unilateral laminoplasty procedure. FIG. 3A is a perspective view of a plate 12 which may be installed to secure the implant 1 of FIGS. 1 & 2, to ensure the implant 1 is not expelled from the cut lamina ends 10. Plate 12 has a length 13, a thickness 14 and a body portion 15 with first and second ends 16A, 16B comprising bone engaging portions 17 and implant engaging portions 18. As shown in FIG. 3A the bone engaging portions 17 and implant engaging portions 18 may consist of the holes adapted for receiving bone screws 19 or hooks 20 (not shown) capable of grasping bone screws installed in the lamina and/or implant. Each side of plate 12 may have one or more bone engaging portions 19 and one or more implant engaging portions 18. In a further embodiment the plate 12 may be flexible to allow the surgeon to form it to the individual contour of the patient's spine, thereby achieving a tight fit between components. The plates may be fabricated from a biocompatable metal or other material known in the art that would be suitable for long term retention of an implant 1.

Instead of a single plate 12, smaller plates without connecting body portion 15 may be utilized, each plate comprising at least one bone engaging portion 17 and one implant engaging portion 18.

FIG. 3B is a side view of the implants 1 installed in FIG. 2A, further showing the installation of optional plates 12 of FIG. 3A. Bone screws 19 are installed to secure the plates 12 to both the respective opposing lamina segment 10, and the implant. In this embodiment, bone screws are also installed in the screw holes 18 of the implant engaging portion, to secure the plates to the implants 1. Also in this embodiment, the plates are flexible and are bent to assume the varying

contour of the lamina segments and the implant. More than one optional plate may be used to secure the implant to the lamina.

FIGS. 4A and 4B show perspective and side views of an allograft implant 30 which incorporates the design features of the implants of FIG. 1, but which further includes a pair of bone flaps 31A, 31B disposed at first and second ends 32A, 32B of the implant 30. These bone flaps are used to secure the implant 30 to the respective cut ends of lamina in a unilateral laminoplasty procedure. At least a portion of each flap comprises demineralized bone. Demineralization of the flaps, but not the implant, provides the implant with flexible attachment points which may be contoured to conform to the shape of the adjacent lamina. Bone flaps 31A, 31B comprise thin, flat, rectangular segments of allograft having an outer surface 34 and a bone engaging surface 35. The outer surfaces 34 of the flaps preferably are the same width as, are contiguous with, and extend axially like wings from the outer surface 36 of the implant 30. In a preferred embodiment, bone flaps 31A, 31B are machined from the same segment of donor bone as implant 30. At least a portion of flaps 31A, 31B may be demineralized using any commercially acceptable process (*e.g.* hydrochloric acid bath, etc.) that will render the resulting flaps flexible. Flaps 31A, B are provided with holes 36A, 36B suitable for receiving bone screws 37A, 37B which are used to secure the bone flaps 31A, 31B and implant 30 to the adjacent cut lamina ends.

In another embodiment, these bone flaps may not be demineralized, but instead each bone flap may comprise a notch 131A, 131B in the respective region where the bone flaps 31A, 31B connect to the implant 30. Notches 131A, 131B may be any type of notch or reduction in the thickness of the bone flap appropriate to provide flexibility for placing the flaps on the adjacent laminae surfaces, while retaining the requisite strength to ensure the bone flaps will not separate from the implant during installation.

FIGS. 5A, 5B and 5C show an embodiment of an implant for use in a bilateral or "french door" laminoplasty procedure, in which the spinous process of a targeted vertebra is bisected along the sagittal plane and the segments separated to enlarge the spinal canal. The implant 40 has a wall 45 having an inside surface 47 and an outside surface 48, and first and second ends 46A, 46B. The outside surface 48 has an outer side region 41 having an outer side length 42 and an inner side region 43

having an inner side length 44. Inside surface 47 communicates with first and second ends 46A & 46B to define a hollow central region 49 of the implant. The implant 40 has a generally trapezoidal shape when viewed from the side (FIG. 5B), and inner side region 43 forms angle "TA" with respect to the first and second ends 46A, 46B. This trapezoidal configuration allows the implant first and second ends 46A, 46B to conform to the cut, angled surfaces of the spinous process segments to which the implant will eventually fuse. Inner side length 44 preferably is from between about 6.0 mm to about 10 mm, and angle "TA" preferably is from between about 50 to about 70 degrees. The implant 40 further has a width "W" which is the distance between the outer side region 41 and the inner side region 43. Implant 40 also has a depth "D" which is the distance between opposing outside surfaces 48 measured along a line drawn perpendicular to a line defining the width "W." Width "W" preferably should be between about 10 mm to about 11.5 mm; and depth "D" preferably should be between about 6.5 mm to about 7.5 mm.

The shape and size of outside surface 48 is not critical and, therefore, any implant external configuration can be used preferably so long as first and second ends 46A, 46B provide sufficient contact area with the cut spinous process segments, does not project out from between the bone segments so far as to interfere with other anatomy, and does not intrude on the spinal cord space For aesthetic purposes and in an attempt to minimize the amount of new material introduced into a patient, however, the outside surface 41 of the implant 40 should preferably not extend beyond the outside surface of the cut spinous process segments. In a preferred embodiment the outside surface 41 of the implant 40 is configured such that the outside surface 41, when viewed from the end, displays the form of a substantially geometric shape (e.g. ellipse, oval, circle, etc.) (FIG. 5C).

In a further embodiment, the inside surface 43 of the implant 40 may be machined so that the hollow central region 49 approximates the configuration and geometry of the implant outside surface 41 (*i.e.* an ellipse or oval). The hollow central area is designed to be packed with osteogenic material such as bone chips, etc. to facilitate fusion of the implant with the patient's cut spinous process segments. Preferably, this center area may be made as large as possible to facilitate the fusion process.

The thickness of wall 45 preferably should be from between about 1.00 to about 1.50 mm; more preferably about 1.25 mm. Preferably the thickness of wall 45 should not be less than about 1.0 mm to ensure the implant retains sufficient strength to withstand the stresses imparted on the spine associated with daily living.

The implant 40 may be fabricated from a biocompatable metal (*e.g.* stainless steel, or titanium, etc.) or polymer, or from allograft material preferably taken from a long bone (*e.g.* femur, tibia, fibula, humerus). Where the implant is fabricated from metal or polymer, it may be provided in a solid form. Preferably, however, the implant should incorporate a hollow region, and the inside surface 44, should be formed to maximize the space available for packing with osteogenic material while maintaining adequate wall thickness. Where the implant is an allograft, the inside surface 44 and hollow center 49 may be defined by the intermedullary canal of the donor bone. The allograft may be left in this state, and the hollow central region 49 packed with osteogenic material. Preferably, however, the inside surface 44 of the allograft will be machined and the hollow central region 49 enlarged to maximize the space available for packing with osteogenic material.

FIGS. 6A and 6B show first and second ends 46A, 46B of implant 40 each incorporating a channel 50 to accept the corresponding arms of a set of distractor pliers (not shown) which may be used to separate the bisected spinous process segments during the bilateral laminoplasty procedure. Each channel 50 has two sidewalls 51 each having a depth "CD", a bottom surface 52 having a width "CW" and a centerline 54 which is formed by a line extending along the implant 40 from inner side region 43 to outer side region 41. Preferably, each channel 50 may incorporate a radiused transition 55 between the sidewalls 51 and the bottom surface 52. In a further preferred embodiment, the channel runs from the inner side region 43 to the outer side region 41 of each end 46A, 46B of the implant. The specific dimensions of the channels is not critical, but should be configured to accept the distractor arms used during the distraction and insertion portion of the procedure. Preferably, the channel bottom surface width "CW" is about 4 mm, and the sidewall depth "CD" is about 1 mm.

FIG. 7 shows a further embodiment of bilateral laminoplasty implant 40, in which first and second ends 46A, 46B comprise surface projections to improve

pre-fusion retention of the implant 40 between respective cut spinous process segments. In a preferred embodiment, a plurality of saw-tooth serrations 56 having a height 58 and a tooth angle 59 are provided. Preferably the serrations are oriented to run vertically when the implant 40 is installed in the patient. Height 58 and tooth angle 59 are defined with respect to the respective planes formed by implant first and second ends 46A, 46B. Height 58 is measured from the trough 60 of each serration, while tooth angle is measured from the plane formed by the implant first and second ends 46A, 46B. Preferably, height 58 is about 0.5 mm, tooth angle 59 is about 45 degrees, and the distance between troughs 60 is about 1.2 mm. While these dimensions and profile are preferred, other suitable surface profiles (*e.g.* pyramidal teeth, etc.) may be used to ensure implant retention.

In a further embodiment of the implant 40 comprising allograft material, first and second ends 46A, 46B may comprise regions of partially, substantially, or fully demineralized cortical bone to further facilitate fusion of the implant to the lamina. Preferably the demineralized bone portion may comprise the entire surface of each first and second ends 46A, 46B of the implant 40. Preferably the depth of the demineralized portion of will be up to about 2 mm.

The implant 40 may also incorporate a plurality of sutures holes 61 (see FIG. 5C) formed through the implant wall 45 to allow the surgeon to secure the implant to the cut spinous process segments. These suture holes 61 may vary in number, size and position, with the only limitation being that their size, position and number preferably should not compromise the strength and integrity of the implant.

FIGS. 8A, 8B and 8C show a further embodiment of an implant for use in a bilateral laminoplasty procedure. Implant 62 has a first and second ends 63A, 63B, an inner side region 68, an outer side region 65, and sides 66 and 67. The implant 62, like the implant of FIG. 5, has a generally trapezoidal shape when viewed from the side (FIG. 8C). Again, this trapezoidal configuration allows the implant first and second ends 63A, 63B to conform to the cut, angled surfaces of the spinous process segments to which the implant will eventually fuse. As such, inner side 68 forms angle "IA" with respect to the first and second ends 63A, 63B. In this embodiment, the implant 62 is an allograft, comprising "tri-cortical" bone taken from the crest of the ilium region of the pelvis. Harvesting bone from this segment of the pelvis provides an implant which naturally comprises a thin region 64 of

cortical bone on outer side 65, and sides 66 & 67. The inner side 68 of the implant, as well as the implant body portion 69 comprise cancellous bone. This combination of bone types allows the surgeon to exploit both the good strength characteristics of cortical bone, and the good osteogenic characteristics of cancellous bone in a single implant. In a further embodiment, the implant 62 comprises a cavity 70 which communicates with implant first and second ends 63A & 63B, and which may be used for packing osteogenic material to promote fusion between the implant and the cut spinous process segments.

In a preferred embodiment of the implant 62 of FIG. 8, the implant first and second ends 63A, 63B comprise surface projections to improve pre-fusion retention of the implant 62 between respective cut spinous process segments. Saw-tooth serrations, similar to those illustrated and described with regard to the implant of FIG. 5, may be provided. Again, other suitable surface profiles (e.g. pyramidal teeth, etc.) may also be provided to ensure implant retention.

In a further embodiment of the implant 62 comprising allograft material, first and second ends 63A, 63B may comprise regions of partially, substantially, or fully demineralized cortical bone to further facilitate fusion of the implant to the lamina. Preferably the demineralized bone portion may comprise the entire surface of each first and second ends 63A, 63B of the implant 62. Preferably, the depth of the demineralized portion of will be up to about 2 mm.

In another embodiment, the implant 62 may incorporate a plurality of sutures holes (not shown) similar to those shown in FIG. 5C, to allow the surgeon to secure the implant to the cut spinous process segments. These suture holes may vary in number, size and position, with the only limitation being that their number, size and position should not compromise the strength and integrity of the implant.

FIGS. 9A and 9B are front and top views of either trapezoidal implants 40, 62 of FIGS. 5, 8 installed in a patient. First and second ends 46A, 46B, 63A, 63B of implant 40, 62 contact cut spinous process segments 72 and 71 respectively. Hinge cuts 73 and 74 in lamina 75, 76 enable the spinous process segments to be "swung out" by the surgeon to facilitate insertion of the implant 40, 62 therebetween.

FIGS. 10A, 10B and 10C show a further embodiment of an implant adapted for use in a unilateral laminoplasty procedure. Implant 77 comprises first and second plate portions 78A, 78B for connecting to the opposing segments of cut lamina produced during a unilateral laminoplasty procedure. First and second plate portions 78A, 78B are connected by an intermediate portion 80. The plate portions further comprise respective first and second bone engaging portions 79A, 79B which are configured to engage the opposing cut lamina segments. In a preferred embodiment, first and second bone engaging portions 79A, 79B comprise arcuate surfaces for engaging and cradling the respective cut lamina ends. Arcuate surfaces are particularly suited for this purpose because their concave shape can engage and retain lamina segments residing along different axes, a phenomenon which occurs during the unilateral laminoplasty procedure when a single lamina is cut and the resulting segments are swung out to enlarge the area available for the spinal cord. The swinging out process results in an angle being formed between the segments, and it is this misalignment which the arcuate surfaces of the bone engaging portions 79A & 79B accommodate.

In a further embodiment, the thickness of the intermediate portion 80 may be smaller than the height of the first and second plate portions 78A, 78B.

Implant 77 may be fabricated from any biocompatable metal (e.g. titanium, stainless steel, etc.) or polymer, or the implant may be formed of allograft material. If allograft is used, the implant 77 preferably should be fabricated from cortical bone.

In a further embodiment of the implant 77 comprising allograft material, first and second bone engaging portions 79A, 79B may comprise regions of partially, substantially, or fully demineralized bone to further facilitate fusion of the implant to the lamina segments. Preferably the demineralized bone portion may comprise the entire surface of each first and second bone engaging portions 79A, 79B. Preferably, the depth of the demineralized portion will be up to about 2 mm.

In another embodiment , the implant 77 may incorporate suture hole 80 to allow the surgeon to secure the implant to the cut spinous process segments. Additional suture holes (not shown) may be provided, and may vary in number, size

and position, with the only limitation being that their size, position and number preferably should not compromise the strength and integrity of the implant 77.

FIGS. 11A, 11B and 11C show a further embodiment of an implant adapted for use in a unilateral laminoplasty procedure. Implant 84 comprises a plate portion 85 having bone engaging portions 86A, 86B, a graft engaging portion 87, and an allograft 91. Bone engaging portions 86A, 86B further comprise a plurality of suture holes 88 configured to allow the surgeon to secure the cut lamina segments to bone engaging portions 86A, 86B Graft engaging portion 87 comprises a graft seating surface 89 and a graft retaining portion 90 configured to retain a correspondingly shaped allograft 91 for engaging the opposing cut lamina segment. In a preferred embodiment, graft retaining portion 90 comprises two raised tabs 92A, 92B, each residing along at least a portion of opposing ends of graft seating surface 89. In a preferred embodiment, raised tabs 92A, 92B are angled slightly toward the center of graft seating surface 89 so as to facilitate retention of allograft 91. Preferably the angle "A" between raised tabs 92A, 92B and graft seating surface 89 will be from about 70 to about 80 degrees; more preferably this angle will be about 75 degrees. Plate portion 85 further comprises a bottom surface 855. When installed, graft 91 comprises the inner side surface of the implant (i.e. the surface which is closest to the spinal canal), while plate bottom surface 855 comprises the outer side surface of the implant (i.e. the surface which faces away from the spinal canal). In a preferred embodiment, bottom surface 855 comprises a convex shape which assumes the rounded contour of the lamina segments. Preferably, this convex surface has a radius of about 18 mm.

Plate portion 85 may be fabricated from any biocompatable metal (e.g. titanium, stainless steel, etc.) or polymer, or it may be made of allograft material. If allograft is used, the plate portion 85 may be fabricated from cortical bone. Graft 91 preferably may be comprised of a cancellous type bone material to facilitate fusion of the implant to the patient's lamina.

FIGS. 12A and 12B show implant embodiments comprising plates configured to attach directly to the opposing cut segments of lamina produced during a unilateral laminoplasty. These plates are further configured to capture segments of allograft and to engage these segments with the opposing cut segments of lamina to facilitate fusion between the implant and the patient's bone. Plate 93

comprises a body portion 94 having a longitudinal axis and first and second ends 95A, 95B, and a graft retaining portion 96, midway between the ends 95A, 95B, preferably approximately midway between ends 95A, 95B. First and second ends 95A, 95B each comprise a bone engaging portion 97. In a preferred embodiment the bone engaging portion at each first and second end comprises at least one hole suitable for receiving a bone screw 98 (not shown). The bone screws are then used to secure the plate 93 to each opposing segment of lamina. In a further embodiment the bone engaging portions may be hooks capable of grasping bone screws that are installed in the lamina segments.

In the embodiment shown in FIG. 12A, the graft retaining portion 96 comprises a plurality of deformable fingers 99 which are initially arrayed flat along an axis perpendicular to the longitudinal axis of the plate 93. These fingers 99 are capable of being deformed to cradle an allograft 100, preferably cylindrical in shape. Allograft 100 preferably has a length sufficient to engage the cut ends of lamina upon installation, and a diameter of size sufficient to be captured by the deformed fingers 99 of the plate 93.

In the embodiment of FIG. 12B, plate 93 has a graft retaining portion 96 which comprises a hollow region 101, preferably rectangular in shape. A correspondingly configured allograft of cancellous bone is provided having a body 102 capable of being received within the hollow region 101, and further having shoulders 103 which extends beyond the hollow region to contact seating surface 104. In a preferred embodiment, shoulders 103 of allograft 100 are secured to plate 93 using a bone screw 98 placed through bone engaging portion 97.

In a preferred embodiment the plate 93 may be flexible to allow the surgeon to form the body 94 to the individual contour of the patient's spine, thereby achieving a tight fit between components. The plate 93 may be fabricated from a biocompatable metal or other material known in the art that would be suitable for long term retention of an implant and graft.

The current invention also provides a method of using an allograft implant according to any of the embodiments shown in FIGS. 1A, 5A, 8A, 10A or 11A which further has partially, substantially, or fully demineralized end segments to promote fusion between opposing segments of lamina or spinous process

produced during a unilateral or bilateral laminoplasty procedure. This method comprises the steps of cutting a targeted lamina or spinous process as required for either a unilateral or bilateral laminoplasty procedure, separating the resulting segments of bone a sufficient distance to allow for insertion of an appropriately sized allograft implant, providing an allograft implant having bone engaging surfaces which comprise partially, substantially, or fully demineralized cortical bone to a depth of up to about 2 mm, and contacting the allograft implant bone engaging surfaces with respective cut segments of lamina or spinous process. This method may be augmented, in the case of a unilateral laminoplasty, to include the additional step of installing a plate over the allograft implant to further assist retention of the implant between the bone segments. Where such a plate is provided, the additional steps of providing bone screws or other fasteners to attach the plate to the opposing segments of bone and/or to attach the plate to the implant, may further be included.

A further embodiment of the above method comprises providing an allograft implant according to the above method, which implant further has partially, substantially, or fully demineralized bone flaps capable of receiving bone screws. Providing such an implant allows the surgeon to affirmatively secure the implant to the cut lamina segments, preferably without the need for a separate plate.

A method of installing a tri-cortical allograft implant as part of a bilateral laminoplasty procedure is also provided. This method comprises the steps of bisecting a targeted spinous process, providing hinge cuts on both adjacent lamina sufficient to allow the spinous process segments to be spread apart, separating the spinous process segments to allow for insertion of an appropriately sized allograft implant, providing an allograft implant having first and second angled bone engaging surfaces which approximate the angle between the bisected and spread spinous process segment cut surfaces, the allograft implant comprising cancellous bone material having a thin outer layer of cortical bone surrounding the cancellous bone, and which cortical bone layer is in communication with the first and second engaging surfaces so as to support the compressive stresses imparted by the cut spinous process segments.

A method of using only a screwed plate to maintain the distance between bone ends produced during a unilateral or bilateral laminoplasty procedure is also provided and described. This method comprises the steps of cutting a

targeted lamina or spinous process as required for the respective laminoplasty procedure, separating the cut bone segments to increase the space available for the spinal canal and associated nerves, providing an appropriately sized plate having first and second ends, wherein each end is configured to allow engagement with the surface of the lamina opposite the surface of the spinal canal and adjacent the cut bone end, and securing first and second ends of the plate to the adjacent bone segments.

In a preferred embodiment of the method, each first and second end of the plate will have at least one recess suitable for receiving a bone screw, wherein the plate is secured to the adjacent cut bone ends using bone screws. In a further embodiment, two plates may be provided to attach to the adjacent cut bone ends.

Accordingly, it should be understood that the embodiments disclosed herein are merely illustrative of the principles of the invention. Various other modifications may be made by those skilled in the art which will embody the principles of the invention and fall within the spirit and the scope thereof.

THE CLAIMS

1. An implant for use in maintaining a desired distance between first and second bisected bone ends of the spinal column, said implant comprising:

(a) a body portion having a length and configured to be insertable between first and second bone ends,
the body portion having an outer surface, and an inner surface defining a substantially hollow portion, the body portion further having an inner side region having an inner side length, and first and second ends which communicate with said hollow portion, the first and second ends comprising bone engaging portions,
at least one of the bone engaging portions comprises surface projections to reduce slippage between the bone engaging portions and the respective said bone segment,

wherein said bone engaging portions are angled with respect to each other.

2. The implant of Claim 1 wherein the intersection between the inner side region and each of the bone engaging portions comprises an angle.

3. The implant of Claim 2 wherein the angle ranges from about 50 to about 70 degrees, and the inner side length ranges from about 6 to about 10 millimeters.

4. The implant of any one of the preceding Claims 1 - 3 wherein the perimeter of the outer surface of the implant is a substantially geometric shape.

5. The implant of Claim 4 wherein the geometric shape is an ellipse having a width and a depth.

6. The implant of Claim 5 wherein the width ranges from about 10.0 to about 11.5 millimeters and the depth ranges from about 6.5 to about 7.5 millimeters

7. The implant of Claims 4 or 5 wherein the geometric shape is a circle.

8. The implant of any one of the preceding Claims 1 - 7, wherein the surface

projections comprise saw tooth ridges.

9. The implant of any one of Claims 1 - 7 wherein the surface projections comprise individual pyramidal teeth.

10. The implant of any one of the preceding Claims 1 - 9, wherein each of the first and second ends further comprises a channel configured to accept the arms of a pair of distractor pliers.

11. The implant of any one of the preceding Claims 1 - 10 wherein the body portion further comprises at least one hollow suture attachment portion to enable a surgeon to secure the implant to at least one of said first and second bone segments.

12. The implant of any one of the preceding Claims 1 - 11 wherein at least a portion of the implant is formed of a bone allograft material.

13. The implant of any one of the preceding Claims 1-12 wherein at least one of the first and second bone engaging portions is comprised of demineralized bone.

14. The implant of Claims 12 or 13 wherein said inner surface is defined by the intermedullary canal of the donor bone.

15. The implant of any one of Claims 12 - 14 wherein said inner surface is configured such that the volume of said substantially hollow portion is greater than the intermedullary canal of the donor bone.

16. The implant of any one of Claims 1 - 11 wherein at least a portion of the implant is fabricated of biocompatable metal.

17. The implant of any one of Claims 1 - 11 wherein at least a portion of the implant is fabricated of biocompatable polymer.

18. An implant for use in the spinal column, the implant comprising:
(a) a body portion having a width, a depth, an inner side region

comprising an inner side length and configured to be insertable between first and second bone segments, the body portion having first and second ends, at least one of the first and second ends comprising a bone engaging portion to engage at least one of the first and second bone segments,

wherein the implant formed of bone allograft material, and at least one of the first and second bone engaging portions is comprised of a demineralized allograft material.

19. The implant of Claim 18 wherein the body portion further comprises a wall having an outer surface, and an inner surface defining a substantially hollow portion, wherein the hollow portion is in communication with the first and second ends.

20. The implant of Claim 19 wherein said hollow portion is defined by the intermedullary canal of the donor bone.

21. The implant of Claims 19 or 20 wherein said inner surface is configured such that the volume of said substantially hollow portion is greater than the intermedullary canal of the donor bone.

22. The implant of any one of the preceding Claims 18 - 21 wherein the at least one of said first and second bone engaging portions further comprises surface projections configured to retain said implant within the first and second bone segments.

23. The implant of Claim 22 wherein the surface projections comprise saw-tooth ridges.

24. The implant of Claim 22 wherein the surface projections comprise individual pyramidal teeth.

25. The implant of any one of Claims 18 - 24 wherein intersection between the inner side region and each of the first and second bone engaging portions comprises an angle.

26. The implant of Claim 25 wherein the angle ranges from about 50 to about 70 degrees, the inner side length ranges from about 6 to about 10 millimeters, the width ranges from about 10 millimeters to about 11.5 millimeters, and the depth ranges from about 6.5 millimeters to about 7.7 millimeters.

27. An implant for use in the spinal column, said implant comprising:
a body portion formed of allograft bone material having an inner side having an inner side length, and configured to be insertable between first and second bone segments of the spine, the body portion having first and second ends, at least one of the first and second ends comprising a bone engaging portion to engage at least one of the first and second bone segments, the at least one bone engaging portion further comprising an outer shell portion substantially surrounding a center region,
wherein the outer shell portion is cortical bone and the center region is cancellous bone.

28. The implant of Claim 27 wherein at least one of the bone engaging portions comprises surface projections to reduce slippage between the bone engaging portions and the respective said bone segment.

29. The implant of Claim 28 wherein the surface projections comprise saw tooth ridges.

30. The implant of Claim 28, wherein the surface projections comprise individual pyramidal teeth.

31. The implant of any one of the preceding Claims 27 - 30 wherein at least one of the first and second bone engaging faces is comprised of demineralized bone.

32. The implant of any one of Claims 27 - 30 wherein the intersection between the inner side and the at least one bone engaging portion comprises an angle.

33. The implant of Claim 32 wherein the angle ranges from about 50 to about 70 degrees, and the inner side length ranges from about 6 to about 10 millimeters.

34. The implant of any one of the preceding Claims 27 - 33 wherein the body portion further comprises a hollow suture attachment portion to enable a surgeon to secure the implant to at least one of said first and second bone segments.

35. An implant for use in the spinal column, said implant comprising:

(a) first and second plates connected by an intermediate portion whose thickness is smaller than the height of the first and second plates, the first and second plates comprising bone engaging portions for engaging first and second bone segments produced during a laminoplasty procedure, the first and second bone engaging portions being angled with respect to each other,

wherein the implant is configured to be insertable between first and second bone segments produced during a laminoplasty procedure.

36. The implant of Claim 36 wherein the first and second plates and the intermediate portion form a substantially U-shaped implant.

37. The implant of Claim 36 wherein the intermediate portion further comprises a hollow suture attachment portion.

38. The implant of any one of the preceding Claims 35 - 37 wherein at least a portion of the implant is comprised of a biocompatable metal.

39. The implant of any one of Claims 35 - 37 wherein at least a portion of the implant is comprised of a biocompatable polymer.

40. The implant of any of the preceding Claims 35 - 39 wherein at least one of the first and second bone engaging portions comprises surface projections to reduce slippage between the bone engaging portions and the respective said bone segment.

41. The implant of Claim 40 wherein the surface projections comprise saw tooth ridges.

42. The implant of Claim 40, wherein the surface projections comprise individual pyramidal teeth.

43. The implant of any one of Claims 35 - 42 wherein at least a portion of the implant is comprised of cortical bone allograft.

44. The implant of any one of Claims 35 - 43 wherein at least one of the bone engaging portions are comprised of demineralized bone.

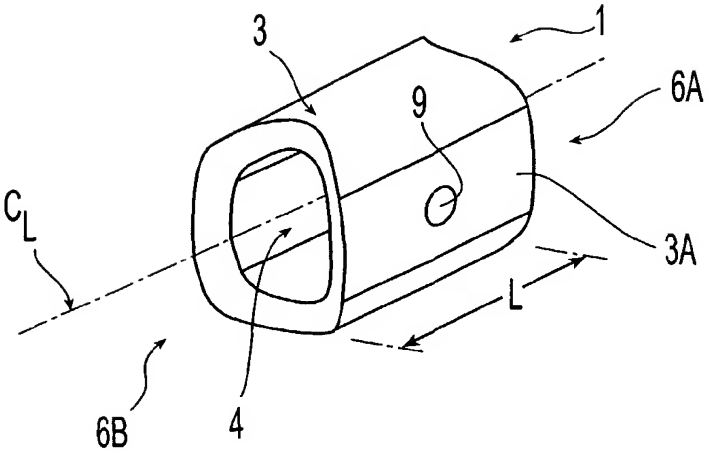


Fig. 1A

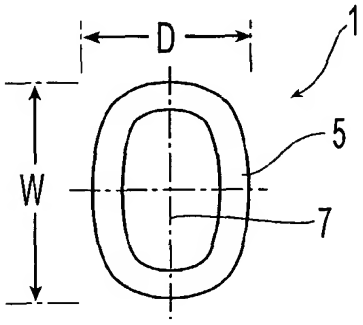


Fig. 1B

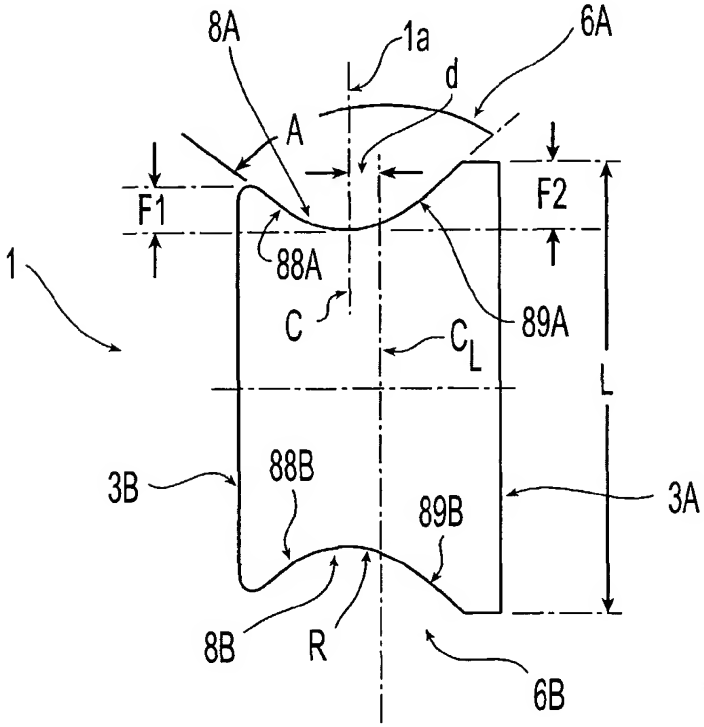


Fig. 1C

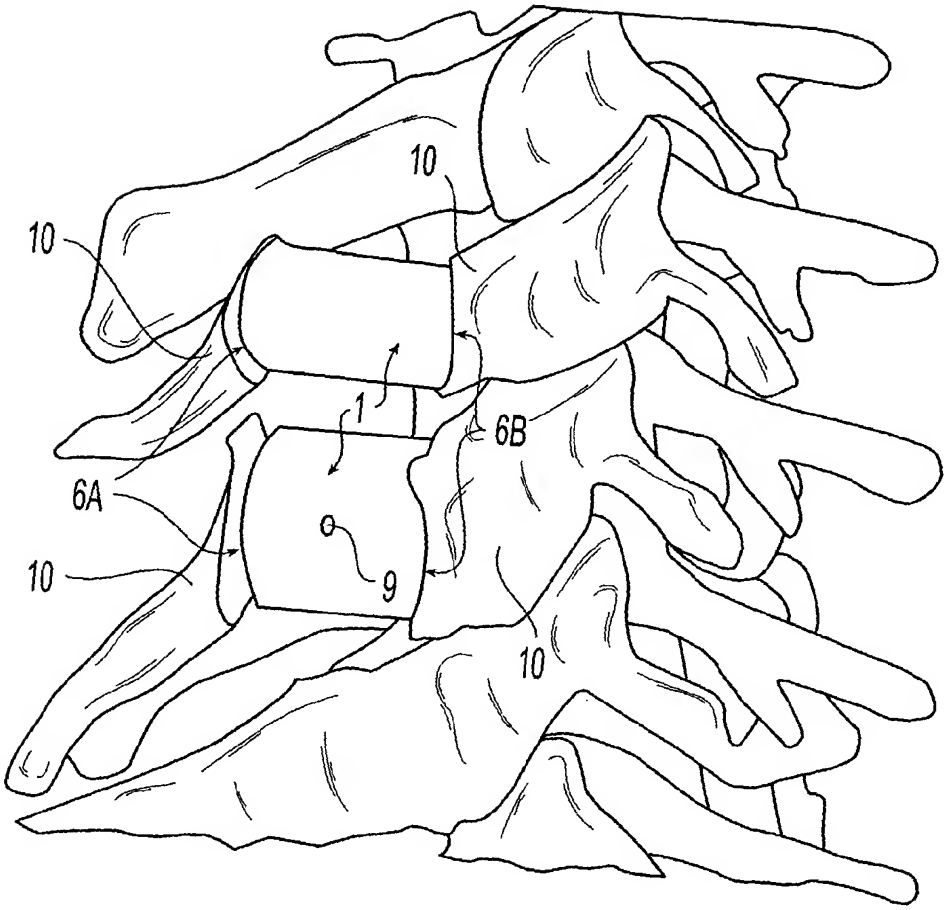


Fig. 2A

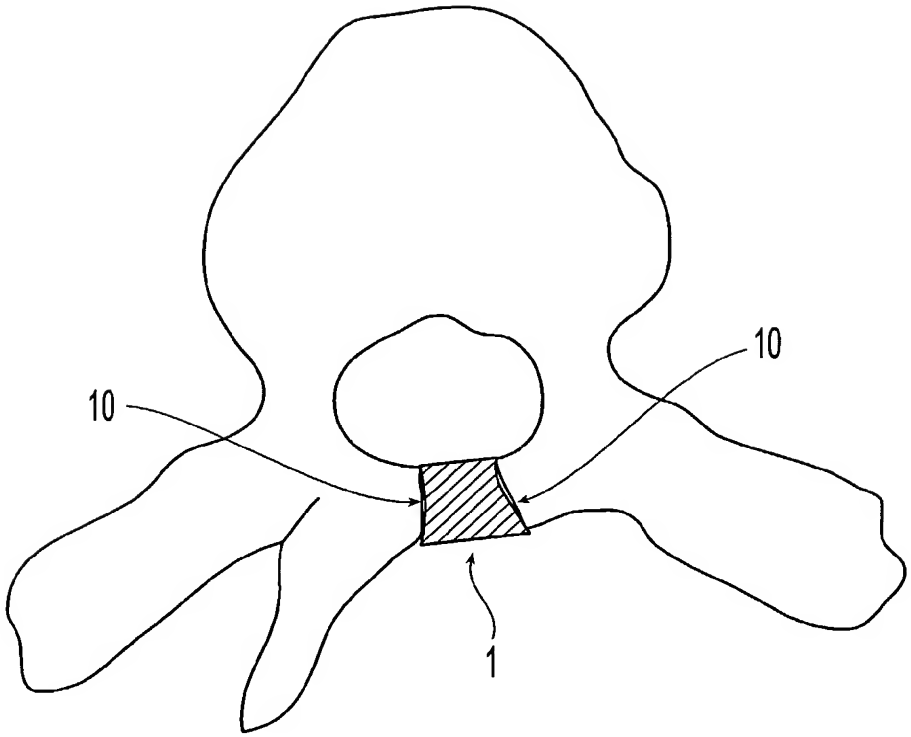


Fig. 2B

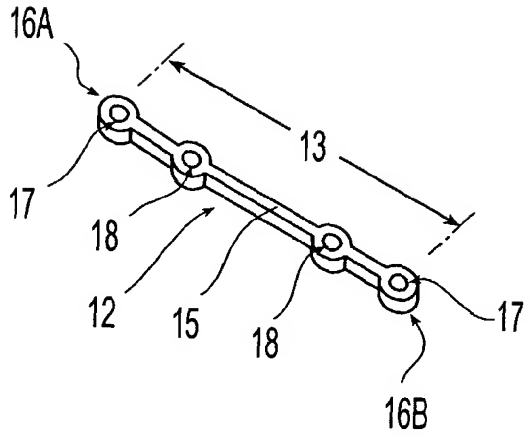


Fig. 3A

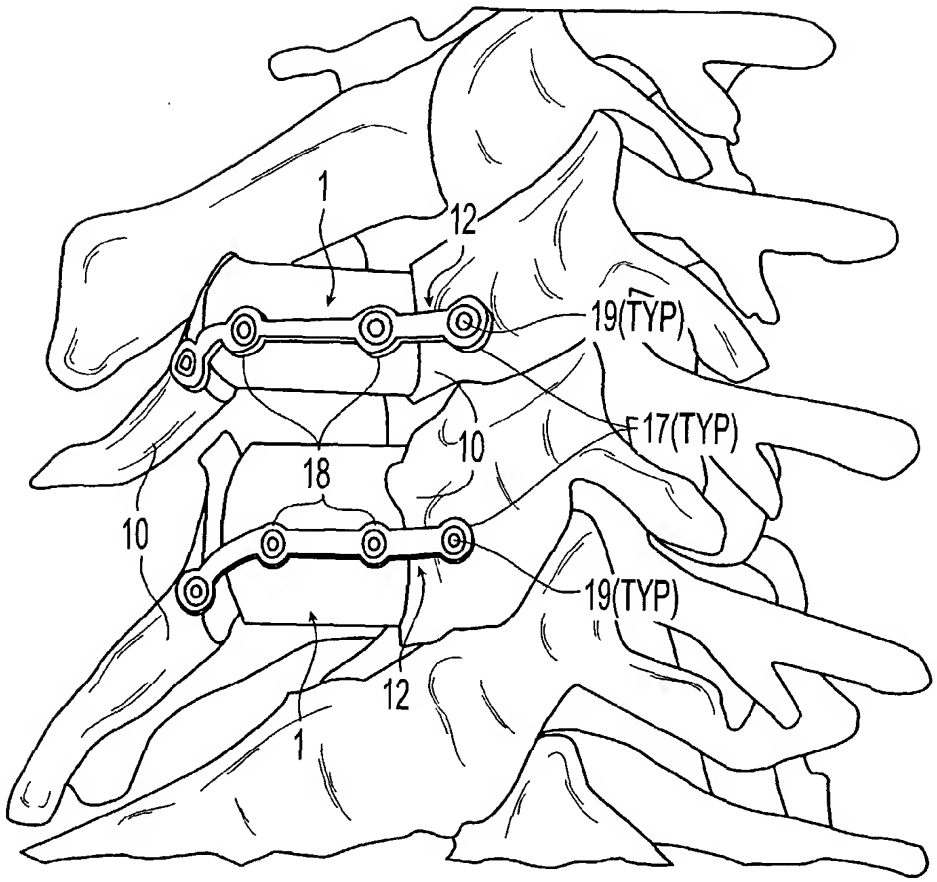


Fig. 3B

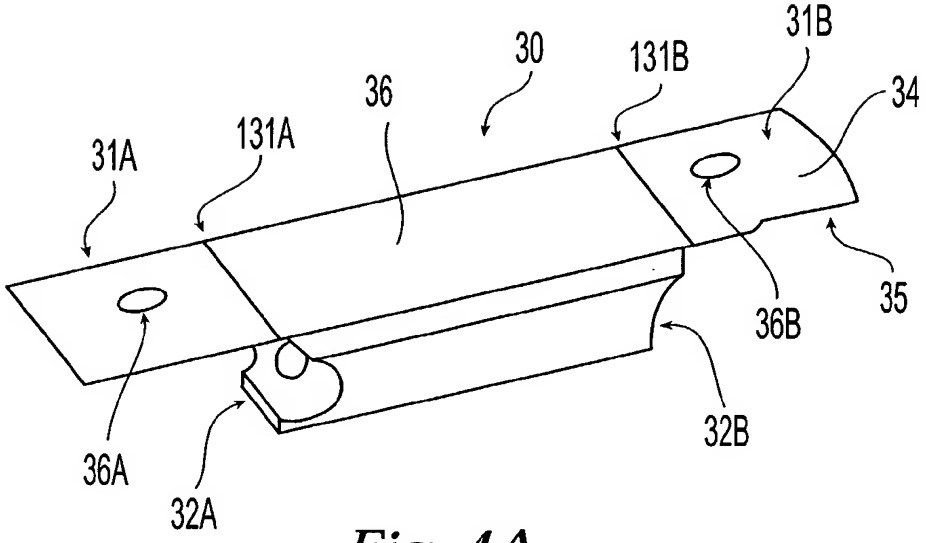
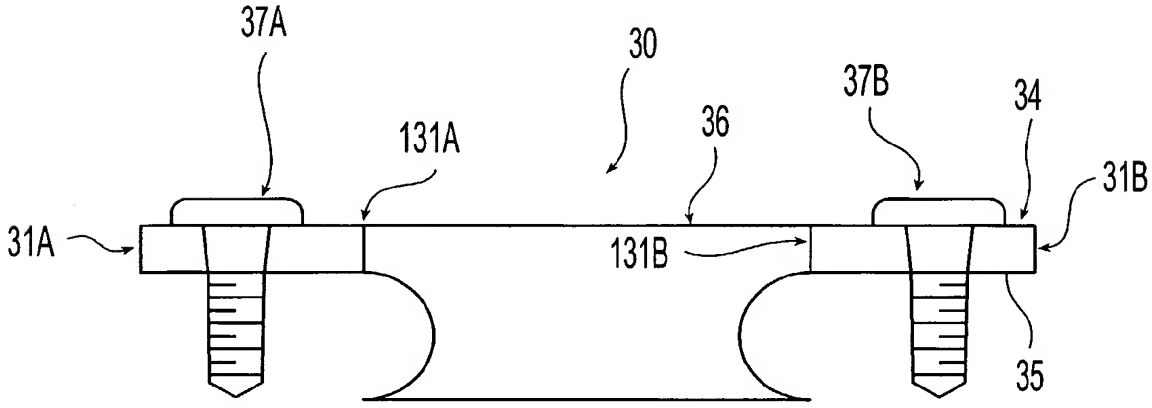

31B
30
131B
36
34
131A
31A
36B
35
36A
32A
32B

Fig. 4A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37B
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131A
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31B
31A
131B
35

Fig. 4B

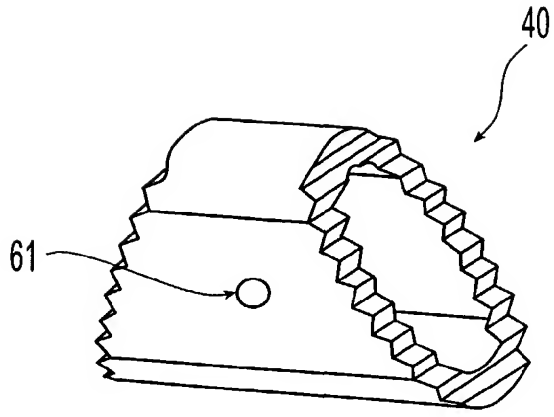

Fig. 5A

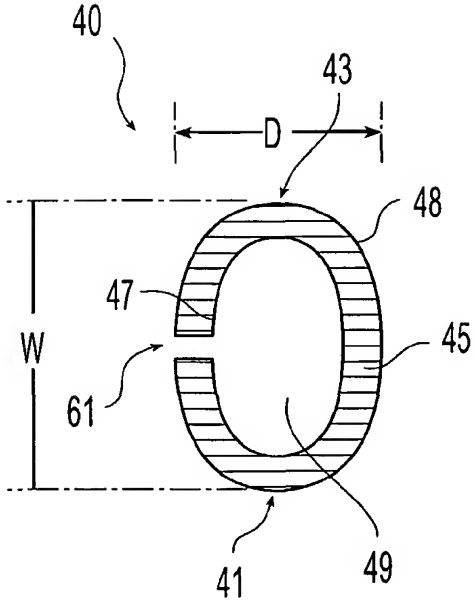

Fig. 5C

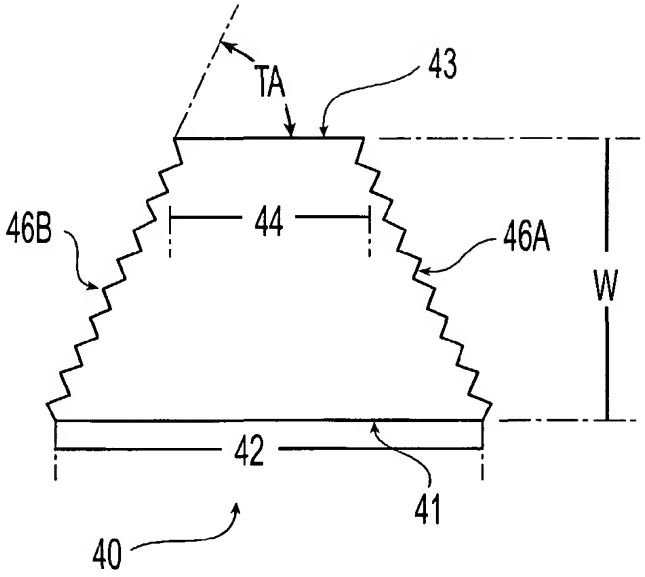

Fig. 5B

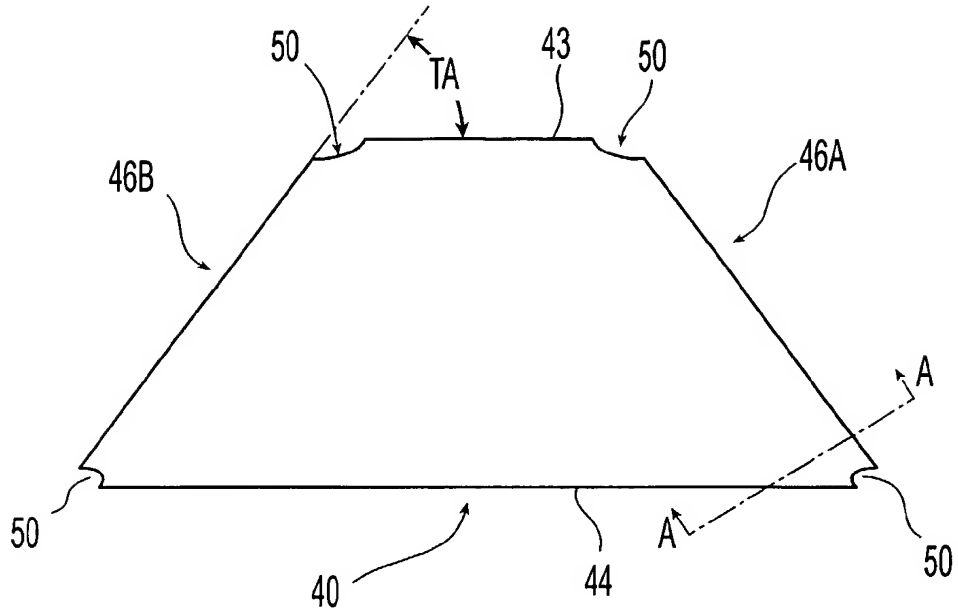

Fig. 6A

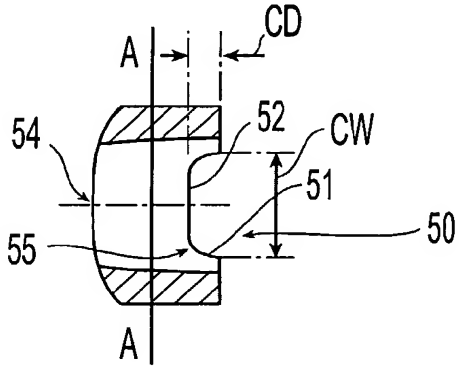

Fig. 6B

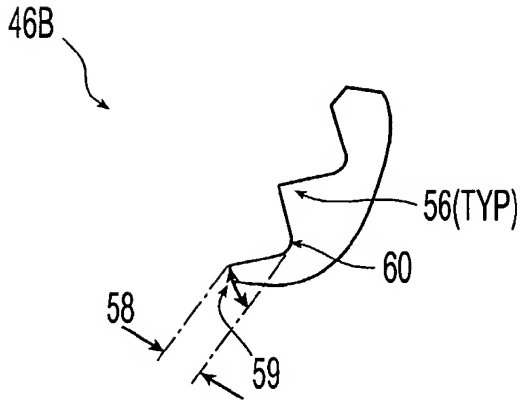

Fig. 7

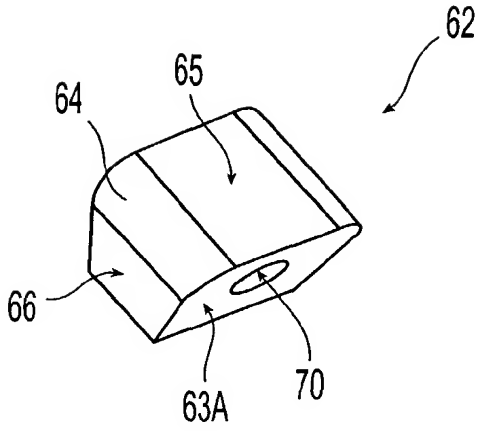

Fig. 8A

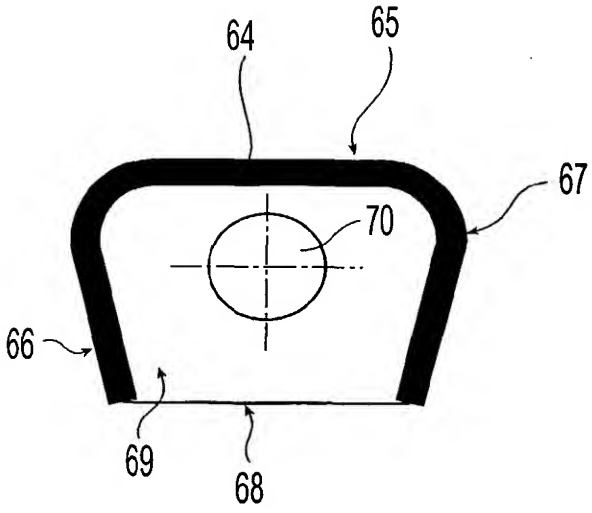

Fig. 8B

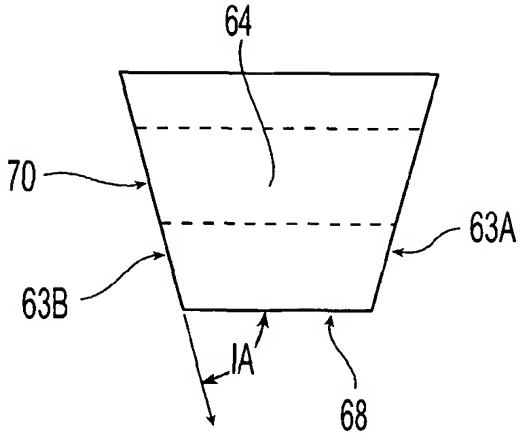

Fig. 8C

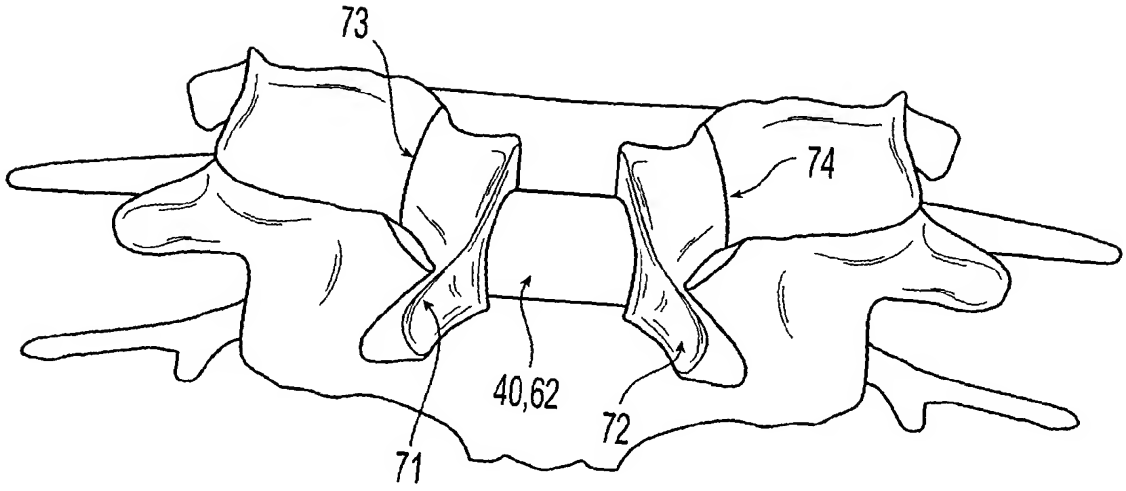

Fig. 9a

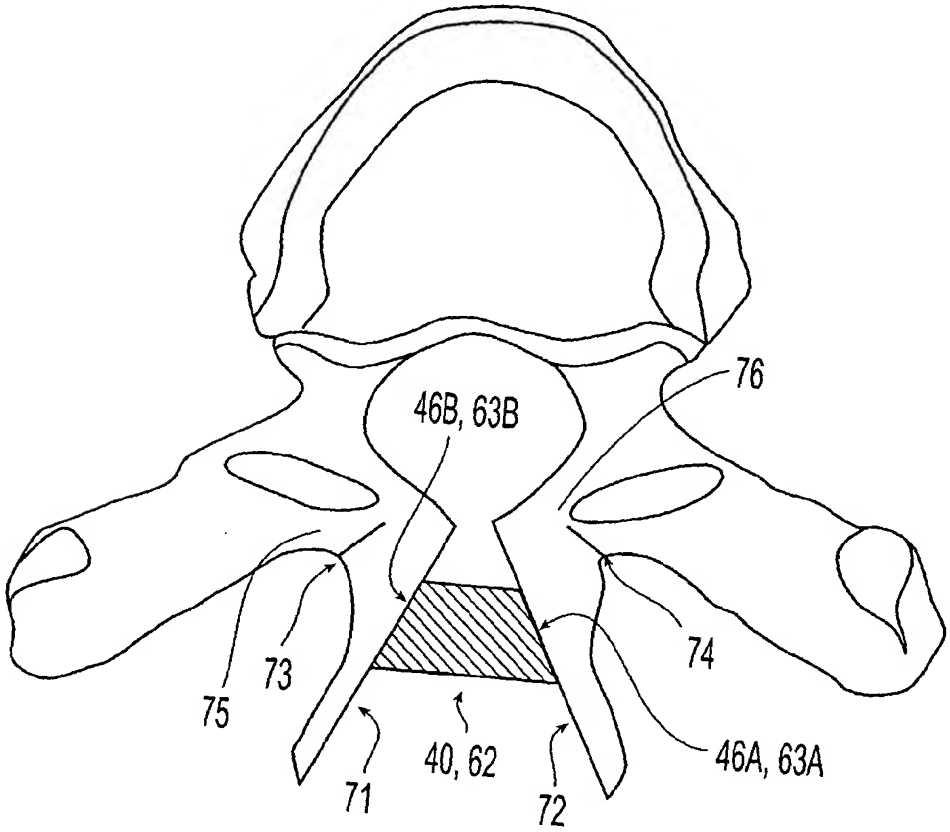

Fig. 9b

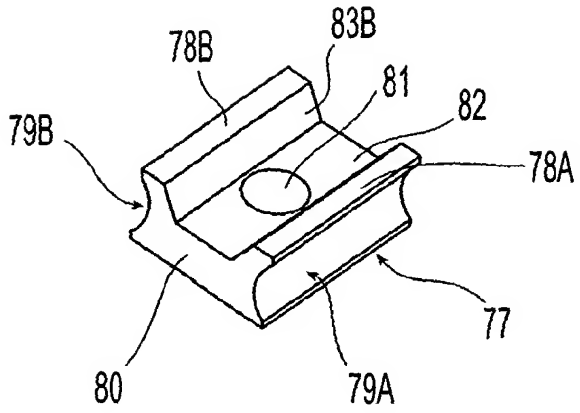

Fig. 10A

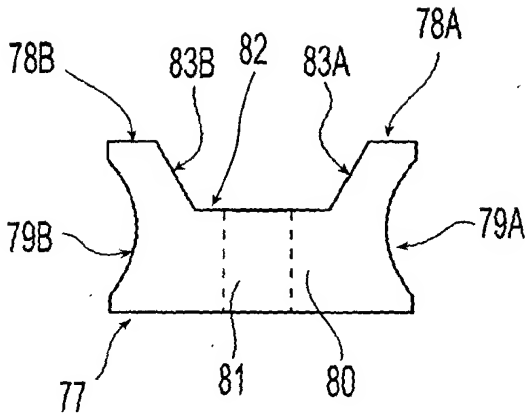

Fig. 10B

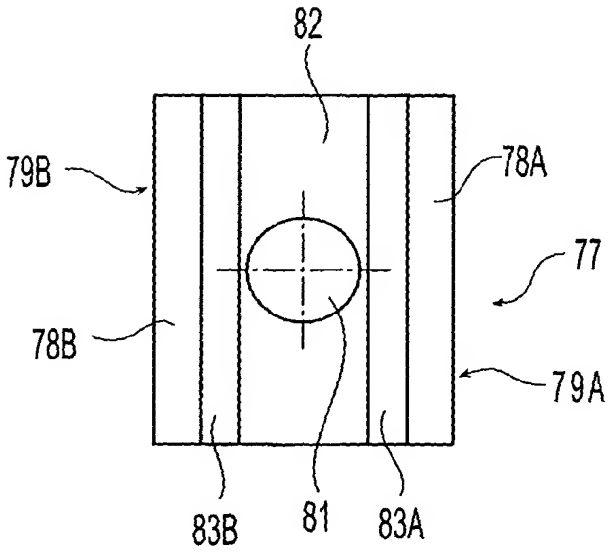

Fig. 10C

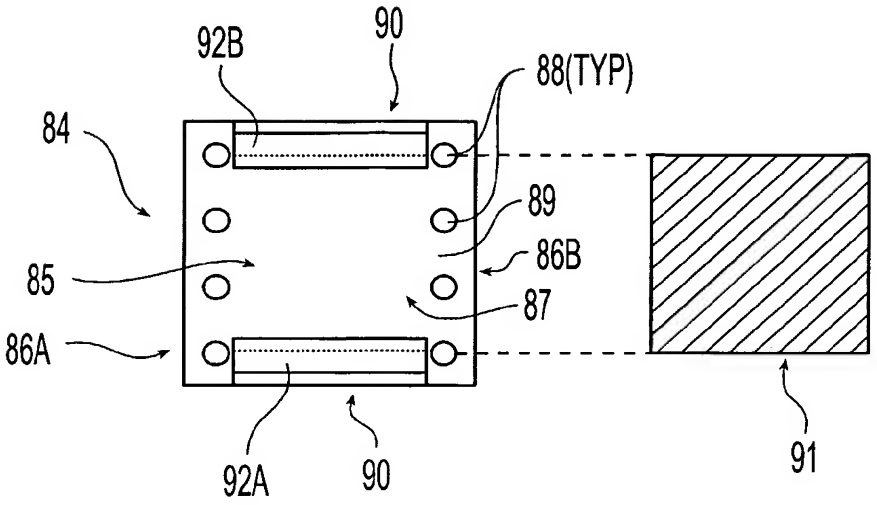

Fig. 11A

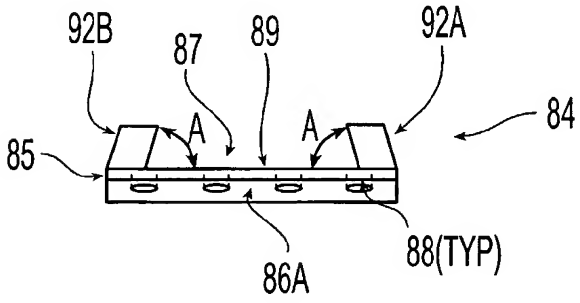

Fig. 11B

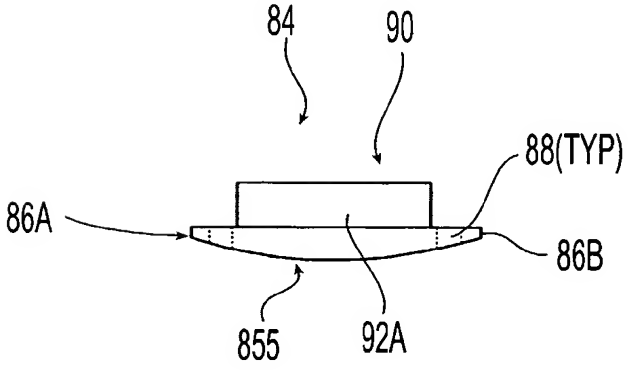

Fig. 11C

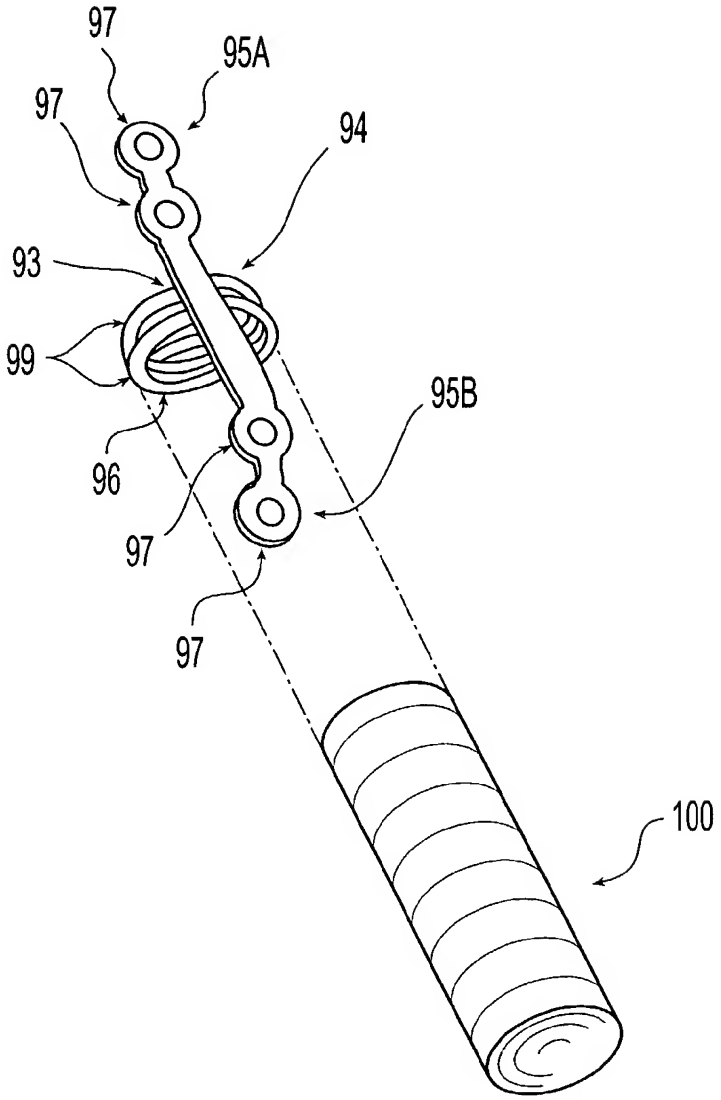

Fig. 12A

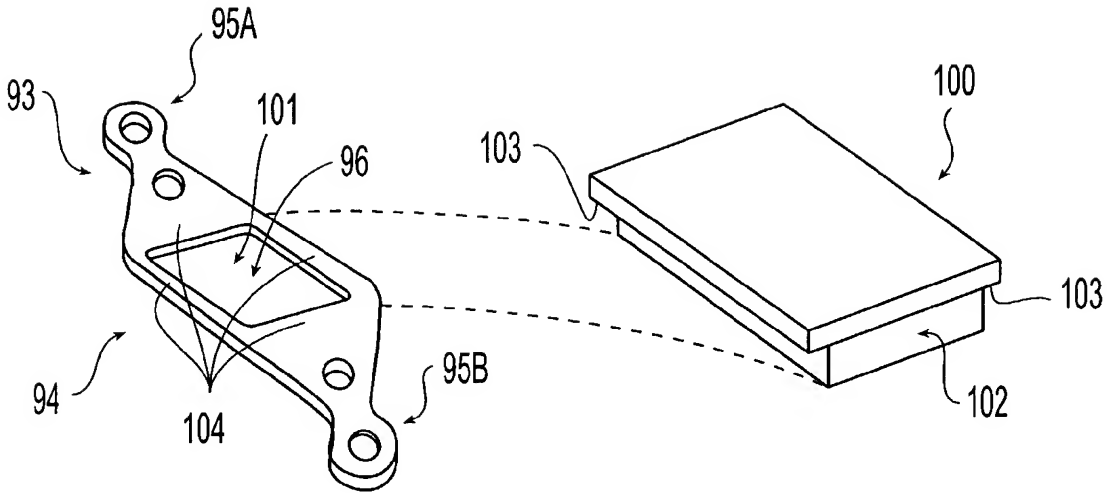

Fig. 12B

INTERNATIONAL SEARCH REPORT

Inte | Application No
PCT/US 02/27359

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/70 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 277 149 B1 (MORRIS JOHN W ET AL) 21 August 2001 (2001-08-21)	1,2,4, 7-9, 12-14, 16-20, 22-25
Y	column 4, line 4 -column 5, line 30 column 6, line 27 - line 30 figures 1,10	15,27-32

X	US 6 143 033 A (BAKER KELLY J ET AL) 7 November 2000 (2000-11-07) column 2, line 64 -column 3, line 23 column 3, line 50 - line 54 column 4, line 8 - line 25 figures 1,4,6,7	1,2,4,5, 9,10,12, 14

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 January 2003	29. 01. 03

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Storer, J

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int Application No
PCT/US 02/27359

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 989 289 A (HOECK JAMES VAN ET AL) 23 November 1999 (1999-11-23) column 6, line 34 - line 39 column 11, line 42 - line 61 figures 10-12,17-19	18-23 15
X	US 6 200 347 B1 (WOLFINBARGER JR LLOYD ET AL) 13 March 2001 (2001-03-13) abstract column 3, line 21 - line 23 column 20, line 23 - line 36 figures 7,13	18,22, 23,25, 35, 38-41, 43,44
X Y	DE 94 13 778 U (SCHAEFER MICOMED GMBH) 4 January 1996 (1996-01-04) page 8, line 1-3 page 9, line 4 - line 8 figures 1,2,4	35,40,41 27-32
P,X	WO 01 70145 A (ELECTRO BIOLOGY INC ;BAILEY KIRK J (US); STRNAD LEE A (US)) 27 September 2001 (2001-09-27) abstract	35,40,42

INTERNATIONAL SEARCH REPORT

ıtional application No.
PCT/US 02/27359

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-34

1.1. Claims: 1-17
An implant for use in maintaining a desired distance between first and second bisected bone ends of the spinal column comprising a body portion having an inner side length and an inner surface defining a substantially hollow portion, the body portion having first and second ends comprising bone engaging portions which are angled with respect to each other.

1.2. Claims: 18-26
An implant for use in the spinal column comprising a body portion having an inner side length and first and second ends, at least one of which first and second ends comprising a bone engaging portion, wherein the implant is formed of bone allograft material and at least one of the first and second bone engaging portions is comprised of demineralised allograft material.

1.3. Claims: 27-34
An implant for use in the spinal column comprising a body portion formed of allograft bone material having an inner side length and first and second ends, at least one of which first and second ends comprising a bone engaging portion comprising an outer shell portion surrounding a centre region, wherein the outer shell portion is cortical bone and the centre region is cancellous bone

2. Claims: 35-44

An implant for use in the spinal column comprising first and second plates connected by an intermediate portion whose thickness is smaller than the height of the first and second plates, the first and second plates comprising bone engaging portions being angled with respect to each other.

Please note that all inventions mentioned under item 1, although not necessarily linked by a common inventive concept, could be searched without effort justifying an additional fee.

INTERNATIONAL SEARCH REPORT

formation on patent family members

Inter ial Application No
PCT/US 02/27359

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(19) World Intellectual Property Organization
International Bureau

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27 September 2002 (27.09.2002)

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(71) Applicant *(for all designated States except US)*: **SULZER SPINE-TECH INC.** [US/US]; 7375 Bush Lake Road, Minneapolis, MN 55439-2029 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BANICK, Christopher, M.** [US/US]; 1370 North Arm Drive, Orono, MN 55364 (US). **DANT, Jack, A.** [US/US]; 1366 Lafond Avenue, St. Paul, MN 55104 (US). **HANSON, David, A.** [US/US]; 2948 Zarthan Avenue South, St. Louis Park, MN 55416 (US). **HOUFBURG, Rodney, L.** [US/US]; 16285 Parkview Drive, S.E., Prior Lake, MN 55372 (US).

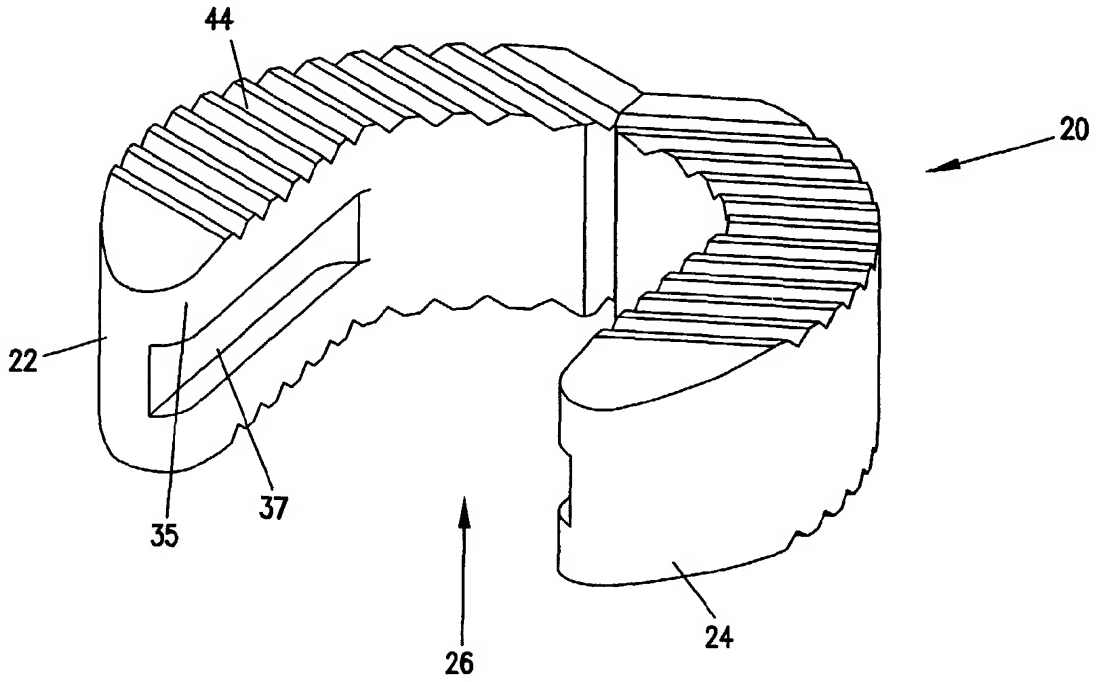
(74) Agent: **PARSONS, Nancy, J.**; Merchant & Gould P.C., P.O. Box 2903, Minneapolis, MN 55402-0903 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: SKELETAL STABILIZATION IMPLANT



(57) Abstract: A spinal implant is described in this disclosure. The implant includes first and second pieces separated by a controlled break location. Spinal implant kits having multiple spinal implant pieces derived from a common source also are disclosed.

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Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SKELETAL STABILIZATION IMPLANT

This application is being filed as a PCT international patent application in the names of Christopher M. Banick, Jack A. Dant, David A. Hanson, and Rodney L. Houfburg, all citizens and residents of the U.S., on 27 September 2002, designating all countries.

Field of the Invention

The present invention relates generally to skeletal implants. More particularly, the present invention relates to implants for stabilizing intervertebral joints.

Background of the Invention

Chronic back problems cause pain and disability for a large segment of the population. In many cases, chronic back problems are caused by intervertebral disc disease. When an intervertebral disc is diseased, the vertebrae between which the disc is positioned may be inadequately supported, resulting in persistent pain. Stabilization and/or arthrodesis of the intervertebral joint can reduce the pain and debilitating effects associated with disc disease.

Spinal stabilization systems and procedures have been developed to stabilize diseased intervertebral joints and, in some cases, to fuse the vertebrae that are adjacent the diseased joint space. Most fusion techniques include removing some or all of the disc material from the affected joint, and stabilizing the joint by inserting an implant (e.g., a bone graft or other material to facilitate fusion of the vertebrae) in the cleaned intervertebral space.

Spinal implants can be inserted into the intervertebral space through an anterior approach, a posterior approach, or postero-lateral approach. The anterior approach involves a surgeon seeking access to the spine through the front (i.e., abdominal area) of the patient. The posterior approach involves a surgeon seeking access to the spine through the back of the patient. The postero-lateral approach is similar to the posterior approach with access coming more from either or both sides of the patient. A variety of different anterior, posterior and postero-lateral techniques are known.

It is often an advantage to use the posterior approach because such an approach typically involves a smaller and less intrusive opening than those required by anterior approach techniques. Because a posterior approach involves a smaller opening, two or more implants are often used in this approach as compared to using a single larger implant. For example, in one technique, adjacent vertebral bodies are stabilized by implanting separate implants between the vertebral bodies on opposite sides of a sagittal plane passing through the midline of the vertebral bodies. When using multiple implants to support adjacent vertebrae, it is desirable for the implants to have similar or identical mechanical properties so that uniform support is provided on both sides of the sagittal plane. In some instances, it also is desirable for the implants to have similar or identical biologic properties (e.g., to reduce the risk of tissue rejection and to enhance the uniformity of creeping substitution).

Summary of the Invention

One aspect of the present invention relates to skeletal implants and skeletal implant kits adapted to ensure that multiple implants used to support opposing vertebrae have been derived from the same source.

A variety of other aspects of the invention are set forth in part in the description that follows, and in part will be apparent from the description, or may be learned by practicing the invention. The aspects of the invention relate to individual features, as well as combinations of features. It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention as claimed.

Brief Description of the Drawings

FIG. 1 is a top, plan view of one embodiment of a spinal implant in accordance with the principles of the present invention;

FIG. 2a is a front, top perspective view of the spinal implant of FIG. 1;

FIG. 2b is a rear, perspective view of the spinal implant of FIG. 1;

FIG. 2c is a front view of the spinal implant of FIG. 1;

FIG. 2d is a side view of the spinal implant of FIG. 1;

FIG. 3 shows the spinal implant of FIG. 1 split into two pieces;

FIG. 4 shows one piece of the spinal implant of FIG. 1;

FIG. 5a is a cross-sectional view taken along section line 5a-5a of FIG. 1;

FIG. 5b is a cross-sectional view taken along section line 5b-5b of FIG. 1;

FIG. 5c is a cross-sectional view taken along section line 5c-5c of FIG. 1;

FIG. 6a-6e show various views of an insertion tool suitable for inserting the spinal implant of FIG. 1;

FIG. 7 is a kit incorporating the spinal implant of FIG. 1;

FIG. 8 is a kit incorporating the spinal implant of FIG. 1 with the spinal implant being separated into two pieces; and

FIGS. 9a and 9b show the spinal implant of FIG. 1 inserted into the intervertebral space between two vertebrae.

Detailed Description

The present invention is directed to skeletal implants, skeletal implant kits and methods for placing implants between bones desired to be fused. It is preferred for the implants to be used for vertebral/spinal applications such as fusing cervical, thoracic and/or lumbar intervertebral joints. In the case of fusing an intervertebral joint, implants in accordance with the principles of the present invention can be implanted using an anterior, posterior or postero-lateral approach to the patient's vertebrae.

As used herein, an "implant" includes any implant suitable for facilitating fusion between adjacent bones and includes implants prepared from known implant materials including, non-bone material such as titanium, stainless steel, porous titanium, bio-glass, calcium phosphate, ceramic, carbon fiber-based polymers, biodegradable and polymers. However, it is preferred for implants in accordance with the principles of the present invention to be derived from natural bone tissue (e.g., allograft and xenograft bone). It is most preferred for implants in accordance with the principles of the present invention to be derived from natural bone such as from a cadaveric allograft bone source. For example, the implants can be derived by cross-sectioning cortical rings from cadaveric allograft bones such as

femur, tibia or fibia bones. Alternatively, the implants can be formed/molded from ground, sintered or composite bone material. Bone tissue cut from a human femur bone is particularly suited for use in practicing the principles of the present invention. Xenograft bones (e.g., from a bovine source) also can be used.

The term "allograft" will be understood to mean a bone implant from a donor transplanted to a genetically dissimilar recipient of the same species. The term "xenograft" will be understood to mean a bone implant from a donor transplanted to a recipient of a different species.

FIG. 1 shows a spinal implant 20 that is an embodiment of the present invention. As shown in FIG. 1, the spinal implant 20 includes first and second pieces 22, 24 (i.e., legs). The first and second pieces 22, 24 include portions opposing one another so as to define an inner pocket 26. The first and second pieces 22, 24 are integrally connected to one another at a central connection location 28. In one embodiment, the implant member 20 has a reduced cross-sectional area at the central connection location 28. The reduced cross-sectional area provides a controlled break location at the central connection location 28. As best shown in FIGS. 5a-5c, the region of reduced cross-sectional area at the central connection location 28 is smaller than nominal cross-sectional areas (average cross-sectional areas) of each of the first and second pieces 22, 24 of the spinal implant member 20.

As shown in FIG. 1, the spinal implant 20 has a generally "C" or "U" shape. The implant member 20 includes a convex outer boundary 30 and an inner boundary 32 having a concave portion 33 and opposing straight portions 35. As shown in FIGS. 2a and 2c, grooves 37 may be cut in the straight portions 35. A fixture fits within the grooves 37 to secure the implant during manufacture of the implant 20. The inner boundary 32 defines the pocket 26 of the implant 20.

Referring again to FIG. 1, a first notch 34 located at the outer boundary 30 of the implant 20 defines the reduced cross-sectional area at the controlled break location. A second notch 36 located at the inner boundary 32 of the spinal implant 20 also defines the reduced cross-sectional area. The first notch 34 is preferably larger than the second notch 36. Both notches 34 and 36 are aligned along an axis of symmetry 38 of the spinal implant 20.

Preferably, the controlled break location is configured to allow the first and second pieces 22, 24 of the implant member 20 to be manually broken or

"snapped" apart without requiring the use of a tool. The controlled break structure ensures that the implant 20 will break at a predetermined location (e.g., at the axis of symmetry 38 for the embodiment of FIG. 1). The implant member 20 can be snapped by manually pulling the pieces 22, 24 apart by applying forces shown by arrows 25. Alternatively, the implant 20 can be snapped by manually pressing the pieces together as shown by arrows 27. Further, the implant member 20 can be broken by manually impacting the controlled break location against a relatively hard surface or edge such as the edge of a surgical instrument tray. In one embodiment, the reduced cross-sectional area provided at the controlled break location is at most 75 percent or, more preferably, about 50 percent of the nominal cross-sectional areas of each of the first and second pieces 22, 24. The controlled break locations can be defined by a variety of techniques for generating a "weaker" region at a desired location. Such weakened region can be formed by techniques such as notching, scoring, etching, cutting, mechanically perforating, laser perforating, etc. Alternatively, the controlled break location can be "weakened" by altering the mechanical properties of the implant material at the controlled break location by techniques such as radiation, demineralization or other techniques.

FIG. 3 shows the spinal implant 20 after the implant has been manually "snapped" at the controlled break location. While it is preferred for the spinal implant 20 to be manually broken, it will be appreciated that tools such as forceps, knives, scissors, saws, clamps or other devices could also be used to split the implant 20 into multiple separate pieces. Further, impact tools such as hammers, chisels or the like also could be used. If tools are desired to be used, a controlled break location may, but need not, be provided. Instead, a line or other demarcation can be used to define a predetermined break location that provides a guide for using the tool.

Although the embodiment of FIG. 1 shows the controlled break location located at the central axis of symmetry of the implant 20, it will be appreciated that other embodiments can include controlled break locations offset from the center of the implant. Further, multiple controlled break locations can be provided to allow the implant to be broken into more than two pieces. Further, in another embodiment, an entire cortical ring is provided having two oppositely

positioned break locations for allowing the implant to be snapped in half to form two separate implants.

Referring again to FIG. 1, the first notch 34 is defined by first and second insertion force application surfaces 40, 42 aligned at an oblique angle relative to one another. The insertion force application surfaces 40, 42 are preferably aligned parallel to grooves 44 formed in top and bottom surfaces of the spinal implant 20. During implantation of the first and second pieces 22, 24, pins of an insertion tool (e.g., see insertion tool 52 of FIGS. 6a-6e) are placed in openings 45 (shown in FIGS. 2b and 6e) defined in the insertion force application surfaces 40, 42. During insertion, insertion forces are applied to the surfaces 40, 42 via the tool 52 to individually push the pieces 22, 24 into the intervertebral space. Particularly for posterior approach techniques, it is desirable for the pieces 22, 24 to be inserted in a direction requiring the smallest possible opening to be defined through the patient's posterior region. For example, arrow 46 of FIG. 4 shows a preferred direction of insertion. It is preferred for the insertion force surfaces 40, 42 to be perpendicularly aligned relative to the preferred insertion directions of their corresponding pieces 22, 24.

The grooves 44 of the implant 20 function to resist migration of the implant upon implantation between opposing bone surfaces. Other structures such as teeth, serrations, cross-cut serrations, notches, bumps, ridges, projections or other surface treatments could also be used.

While the implant 20 can have a constant thickness, it is preferred for the implant 20 to be slightly tapered. In one embodiment, the spinal implant 20 can be tapered about 3 degrees such that a front end 48 of the implant 20 has a thickness T_f that is greater than a thickness T_r located at a rear end 50 of the implant 20. The thicknesses T_f and T_r are labeled in FIG. 2d. In another embodiment, the front end 48 of the implant 20 may be chamfered to facilitate insertion.

FIGS. 6a-6e show an insertion tool 52 suitable for individually implanting the first and second pieces 22, 24 of the spinal implant 20 into the intervertebral space of a patient. The insertion tool 52 includes an insertion end 55 having two parallel pins 57 adapted to fit within the openings 45 defined by the force application surfaces 40, 42 of the implant pieces 22, 24. The tool 52 also includes a curved retaining surface 59 adapted to contact and complement a portion

of the outer boundary 30 of the implant piece 22, 24 when the implant piece 22, 24 is mounted at the insertion end 55.

While other materials could be used, the spinal implant 20 is preferably derived from an allograft bone. In one embodiment, the implant 20 is a transverse cross-section from the femur of a cadaver, and includes a cortical ring. After the ring has been cross-sectioned, relatively soft bone tissue and marrow from the interior of the ring is preferably removed. Next, a portion of the outer cortical ring is removed (e.g., by a technique such as mechanically cutting with a blade or abrasion tool, laser cutting, etching, etc.) to provide the open end of the pocket 26 of the "C" shaped implant 20 (see Fig. 1). Bone removal techniques are then also used to shape the outer and inner boundaries 30, 32 and to form the notches 34, 36. While the particular shape depicted in FIG. 1 is preferred, it will be appreciated that other shapes also could be used without departing from the principles of the present invention.

FIG. 7 illustrates a kit 60 that is an embodiment of the present invention. The kit includes the spinal implant 20, the insertion tool 52 and instructions of use. The components are contained within a sterile package 66 (e.g., a bag, plastic container or other sealed holding configuration). In other embodiments, the kit includes the spinal implant 20, alone, within the sterile package.

FIG. 8 shows another kit 60' that is an embodiment of the present invention. Similar to the embodiment of FIG. 7, the kit 60' includes the spinal implant 20, the insertion tool 52 and the instructions of use 64. Also similar to the embodiment of FIG. 7, the various parts are held within a sterile package 66. However, in the embodiment of FIG. 8, the spinal implant 20 has been pre-broken into the first and second pieces 22, 24. Preferably, both the first and second pieces 22, 24 were derived from the same source. For example, preferably the first and second pieces 22, 24 were provided from human bone tissue from the same cadaver. More preferably, the pieces 22, 24 were provided from the same cortical ring of the same bone. By packaging two or more implant pieces from the same source in one package, the surgeon that ultimately uses the implants will be assured that the pieces will exhibit similar or identical mechanical and biological properties. Further, by using bone pieces from the same donor, the risk of transferring disease to the patient

is reduced by 50 percent as compared to using bone samples from two different donors. In other embodiments, the kit 60' includes the first and second pieces 22, 24, alone, within the sterile package.

The configuration of the implant of FIG. 1 provides similar advantages. For example, because the first and second implant pieces 22, 24 can be provided to a surgeon in an integrally connected configuration, the surgeon can be assured that the two pieces were derived from the same bone source. Further, the configuration of the controlled break location allows the surgeon to quickly and easily separate the two pieces without requiring a tool. In the event the implant is made of a non-bone material, the configuration ensures the surgeon that the implant pieces 22, 24 were manufactured in the same lot.

To implant the spinal implant 20, a diseased disc between two adjacent vertebrae 72, 74 is preferably removed using a conventional discectomy procedure (i.e., partial or complete discectomy). Opposing end plates 72' and 74' of the vertebrae 72, 74 are then preferably prepared to provide relatively flat contact surfaces. The end plates 72', 74' are then conditioned (e.g., with a rasp) to provide a more uniform and osteoconductive/osteoinductive site for the implant 20. After the implant site has been prepared, the sterile package of the kit 60 is opened, allowing the surgeon to access the implant 20. Preferably, the implant 20 is then manually "snapped" or broken into two pieces. One of the pieces 22 is then placed on the insertion tool 52. With the insertion tool, the surgeon inserts the first piece 22 into the cleared intervertebral space between the vertebrae 72, 74. Preferably, the first piece 22 is inserted using a posterior approach. As the first piece 22 is inserted, an insertion force is transferred through the insertion tool 52 to the insertion force surface 40 of the first implant piece 22. As shown in FIGS. 9a and 9b, the first implant piece 22 is preferably positioned on one side of a sagittal plane 80 that passes through the midline of the vertebrae 72, 74. Once the first implant piece 22 has been inserted, the tool 52 is withdrawn from the implant piece 22 and the second implant piece 24 is preferably inserted using the same procedure. However, the second implant piece 24 is preferably positioned on the opposite side of the sagittal plane 80. As mounted in the intervertebral space, the front end 48 of the implant 20 is preferably located at an anterior position relative to the rear end 50. To further promote fusion, additional bone material (e.g., cancellous allograft or autograft

material) or other osteoconductive/osteoinductive material can be placed in the intervertebral space corresponding to the inner pocket 26 of the implant 20. This material can be placed in the intevertebral space before insertion of the first implant piece 22, after insertion of the first implant piece 22, but before insertion of the second piece 24, and/or after both implant pieces 22, 24 have been implanted.

It will be appreciated that the kit 60' can be used in essentially the same manner as the kit 60, except the kit 60' does not require the surgeon to manually break the spinal implant 20 into the separate first and second pieces 22, 24. In both embodiments, the surgeon can be assured that both the first and second pieces 22, 24 of the spinal implant 20 were derived from the same donor source.

With regard to the foregoing description, it is to be understood that changes may be made in detail without departing from the scope of the present invention. It is intended that the specification and depicted aspects of the invention may be considered exemplary, only, with a true scope and spirit of the invention being indicated by the broad meaning of the following claims.

WE CLAIM:

1. A skeletal implant comprising:

an implant member including a predefined break location.

2. The implant of claim 1, wherein the implant member is a spinal implant member.

3. The implant of claim 1, wherein the implant member includes bone tissue.

4. The implant of claim 3, wherein the implant member is from an allograft bone source.

5. The implant of claim 1, wherein the predefined break location is configured to allow the implant member to be manually broken into separate pieces without the use of a tool.

6. The implant of claim 1, wherein the predefined break location comprises a notch located between first and second portions of the implant member, and wherein the predefined break location has a reduced cross-sectional area as compared to nominal cross-sectional areas of the first and second portions of the implant member.

7. The implant of claim 6, wherein the reduced cross-sectional area is at most about 75 percent of the nominal cross-sectional areas of each of the first and second portions.

8. The implant of claim 1, wherein the predefined break location comprises a notch defined in the implant member.

9. The implant of claim 6, wherein the first and second portions each include an insertion force application surface, the insertion force application surface of the first portion being aligned generally perpendicular to an intended line of insertion of the

first portion, and the insertion force application surface of the second portion being aligned generally perpendicular to an intended line of insertion of the second portion.

10. The implant of claim 9, wherein the insertion force application surfaces of the first and second portions are configured to define the notch of the implant.

11. The implant of claim 1, wherein the predefined break location is provided at an axis of symmetry of the implant member.

12. The implant of claim 3, wherein the bone tissue is from a femur bone.

13. The implant of claim 6, wherein the implant member includes a convex outer boundary and a concave inner boundary, and wherein the reduced cross-sectional area includes a first notch at the outer boundary.

14. The implant of claim 13, wherein the reduced cross-sectional area includes a second notch at the inner boundary.

15. The implant of claim 14, wherein the first notch is larger than the second notch.

16. The implant of claim 15, wherein the controlled break location is provided at an axis of symmetry of the implant member.

17. The implant of claim 1, wherein the implant member is generally "C" shaped.

18. A method of manufacturing a skeletal implant, the method comprising:
isolating a segment of bone; and
forming a controlled break location in the segment of bone.

19. The method of claim 18, wherein the bone is from an allograft bone source.

20. The method of claim 18, wherein the controlled break location is formed by forming a notch in the segment of bone.

21. The method of claim 20, wherein the segment of bone has an axis of symmetry separating first and second portions, wherein a first notch is formed in an outer surface of the segment and a second notch is formed in an inner surface of the segment, the first and second notches being aligned along the axis of symmetry.

22. A skeletal implant kit comprising:

a first implant portion derived from a bone source;

a second implant portion derived from the same bone source as the first implant portion; and

a package containing the first and second implant portions.

23. The skeletal implant kit of claim 22, wherein the first and second implant portions are provided as separate pieces.

24. The skeletal implant kit of claim 22, wherein the first and second implant portions are connected at a predefined break location, forming a unitary implant.

25. The skeletal implant kit of claim 24, wherein the unitary implant is manually breakable.

26. The implant kit of any of claims 22-25, wherein the bone source is a cadaveric femur bone.

27. The implant kit of any of claims 22-25, wherein the first and second implant portions are substantially the same size and shape.

FIG. 1

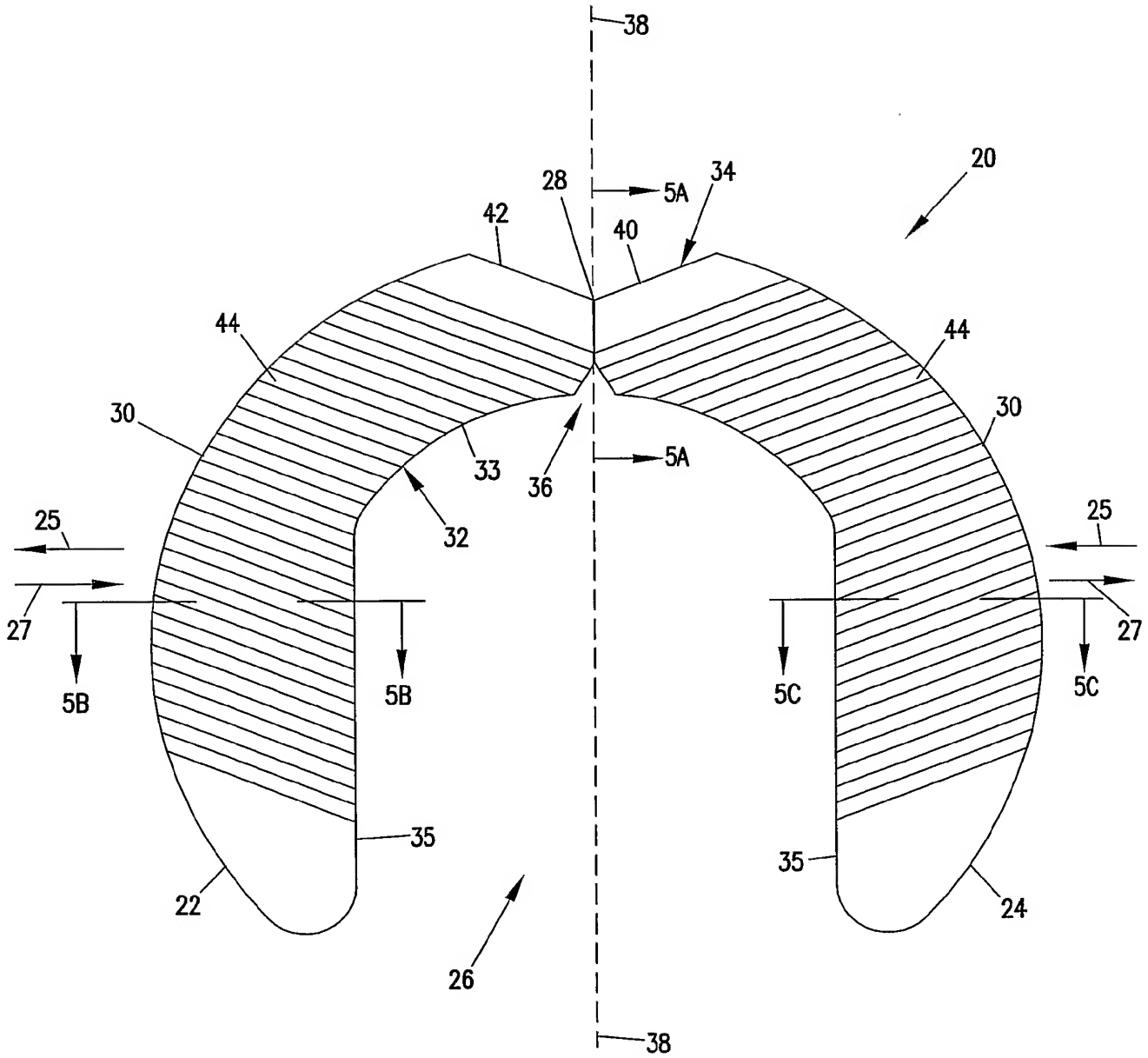
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FIG. 2A

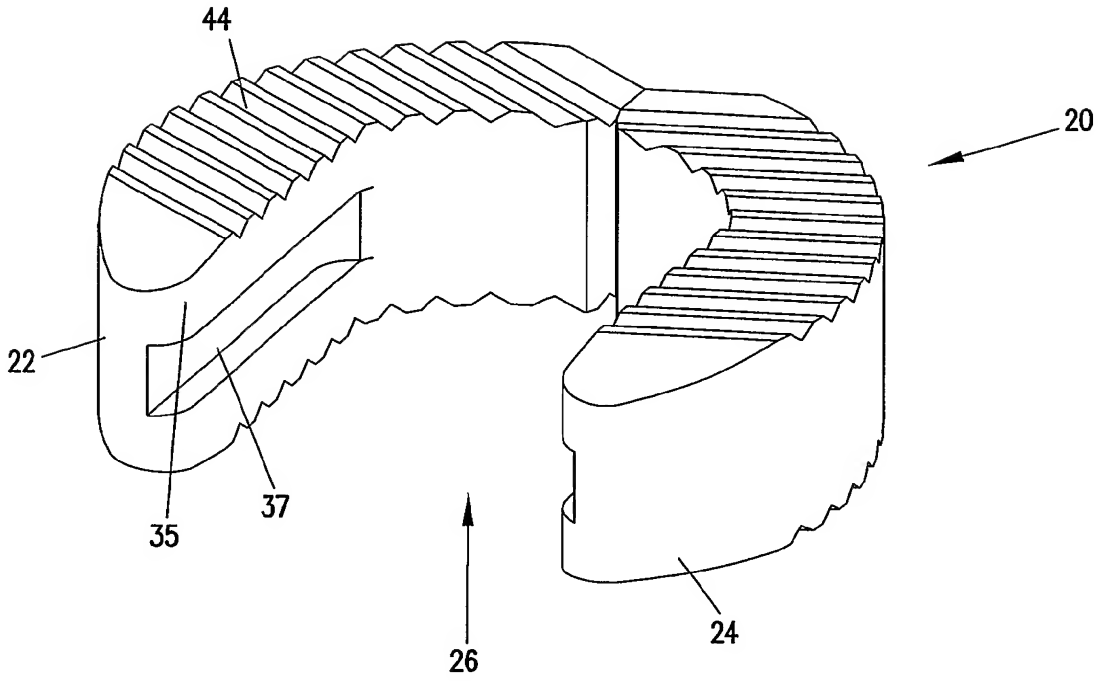


FIG. 2B

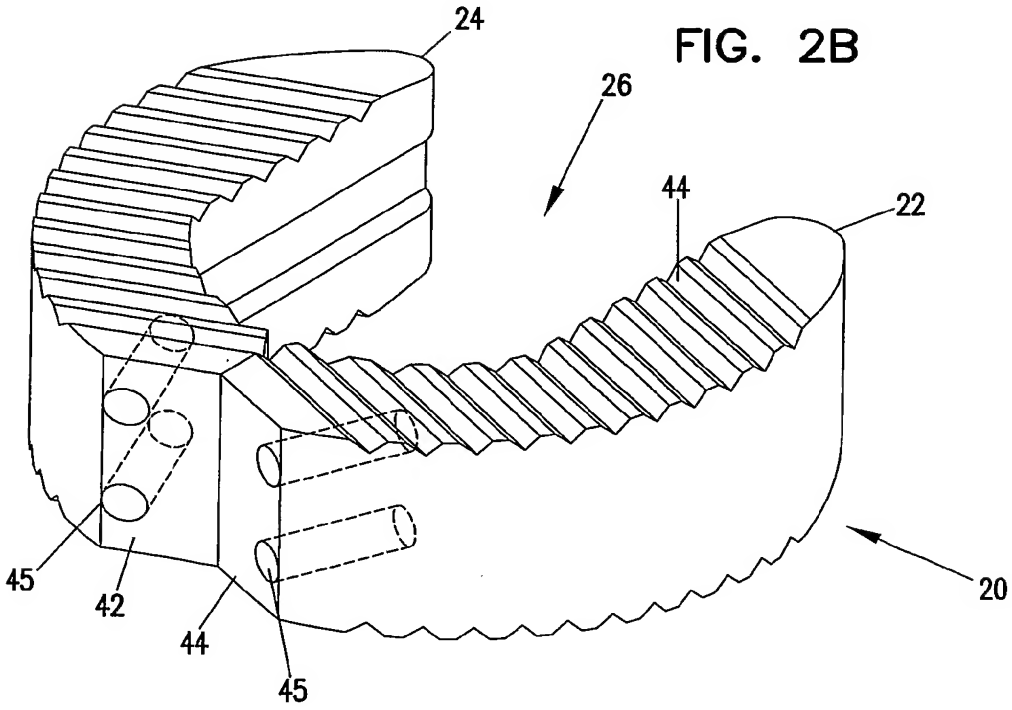


FIG. 2D

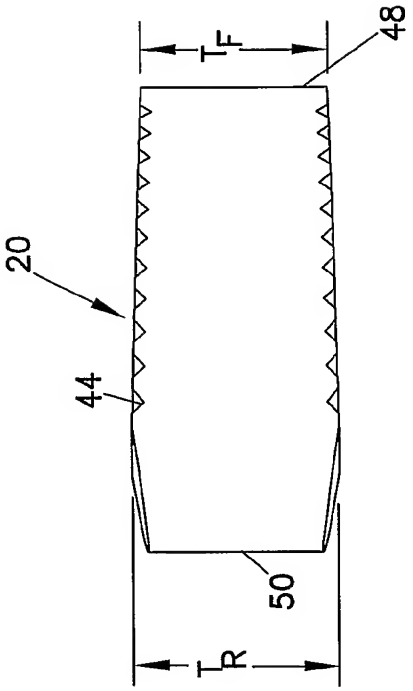


FIG. 2C

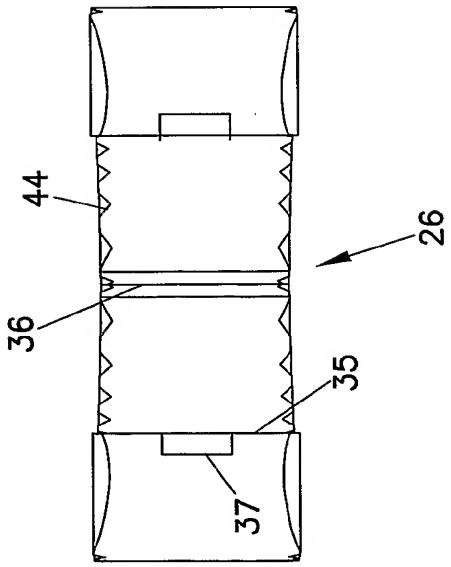
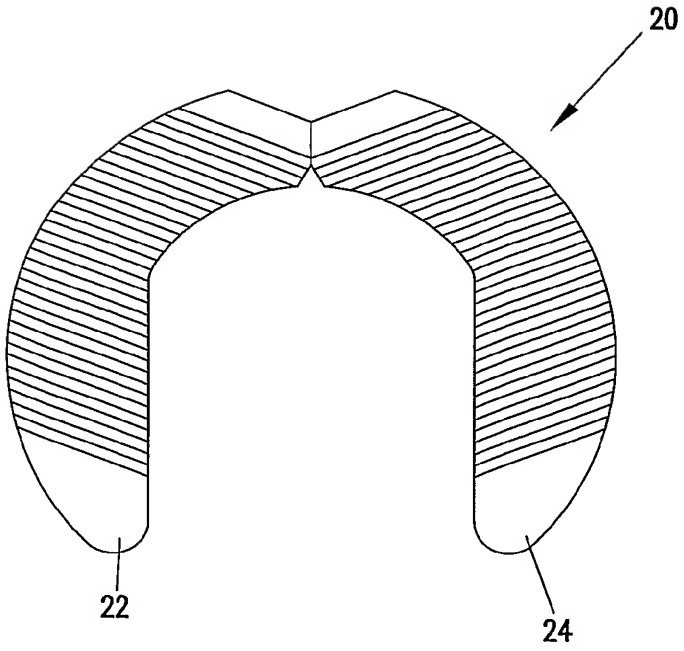


FIG. 3



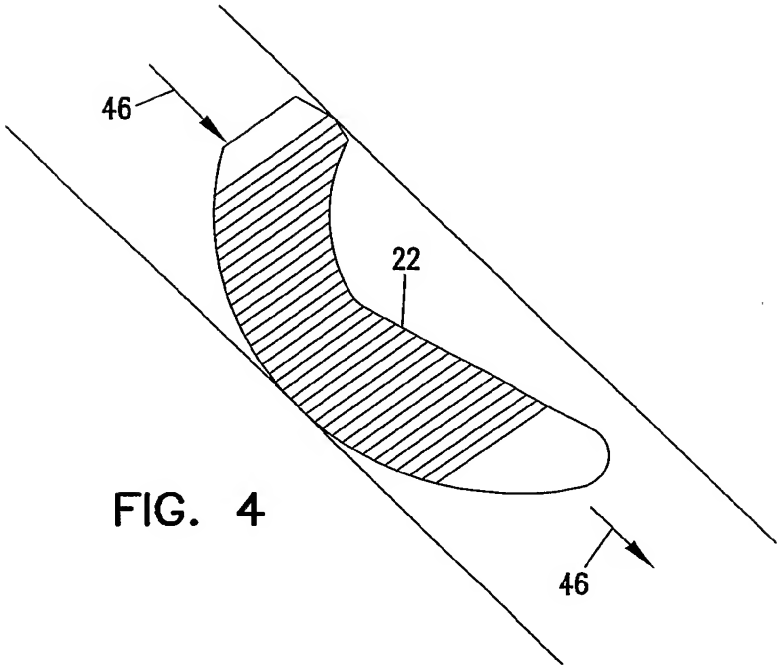


FIG. 4

FIG. 5A

FIG. 5B

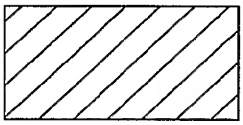


FIG. 5C

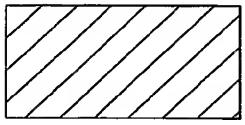


FIG. 6D

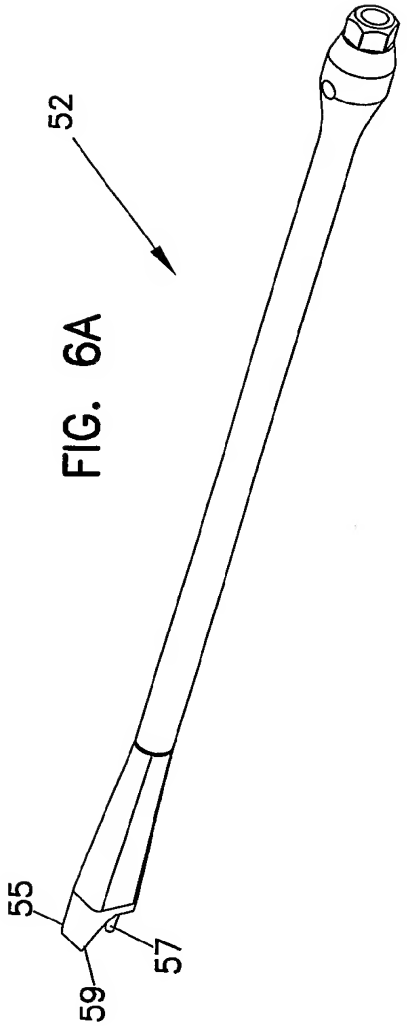


FIG. 6A

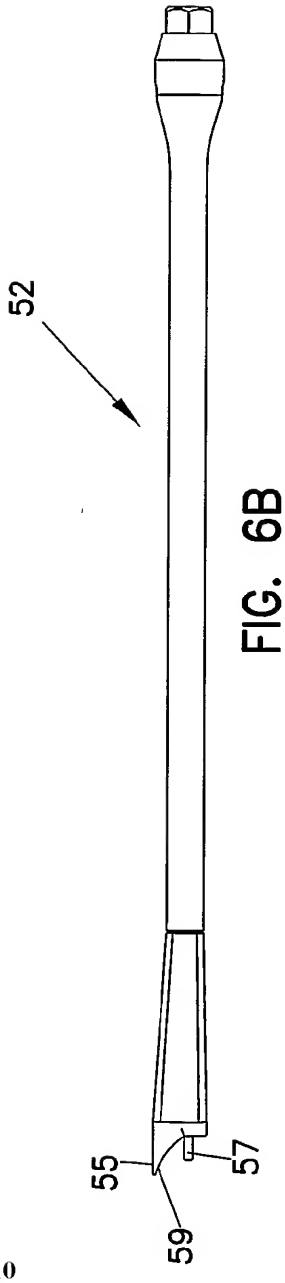


FIG. 6B

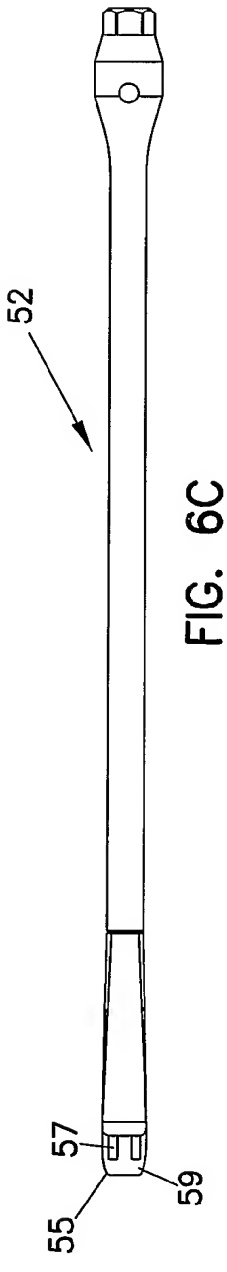
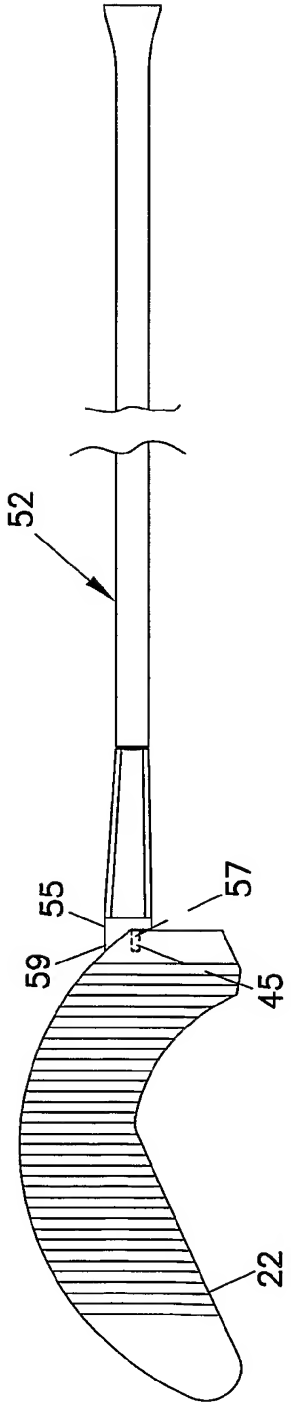


FIG. 6C

FIG. 6E



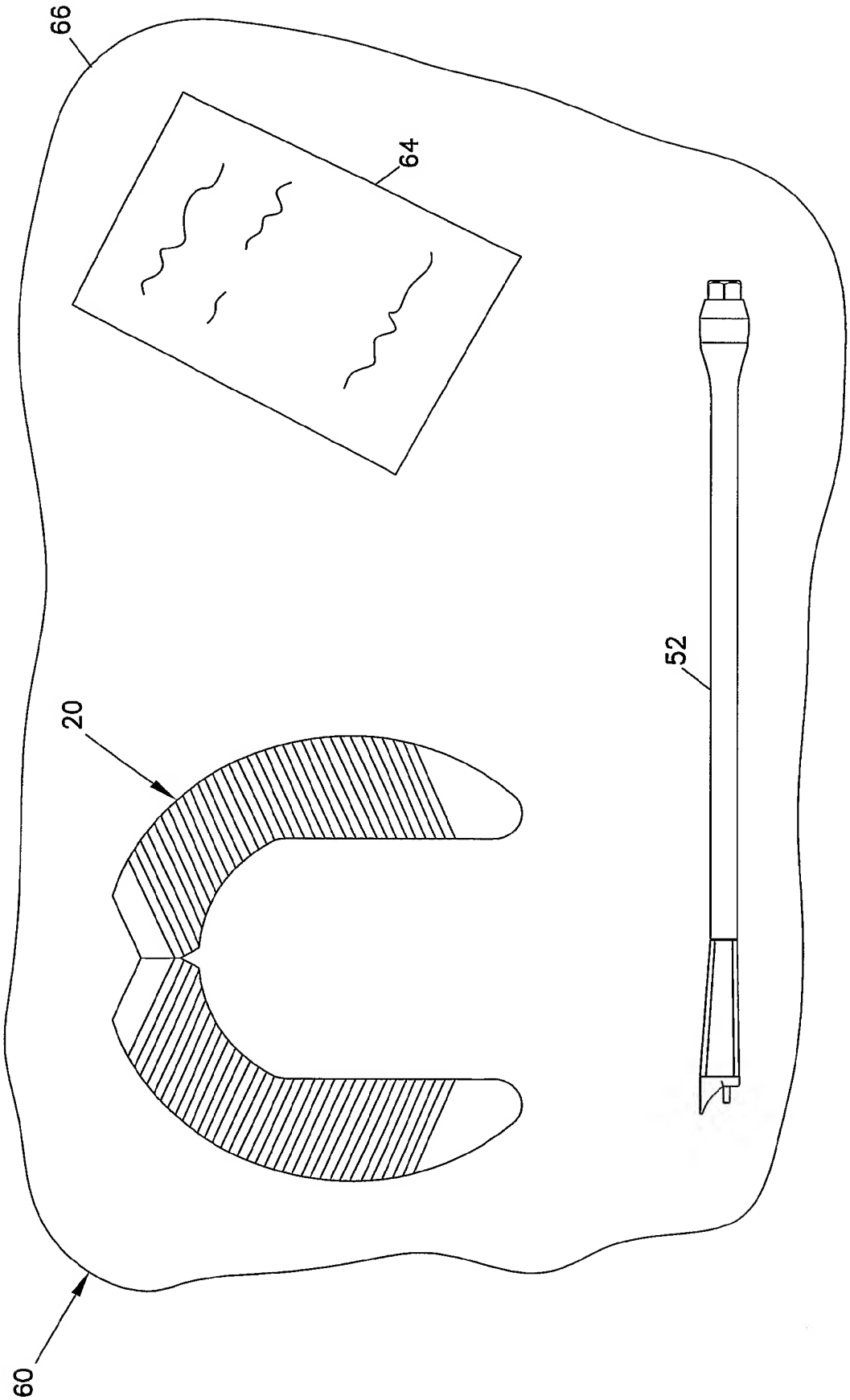


FIG. 7

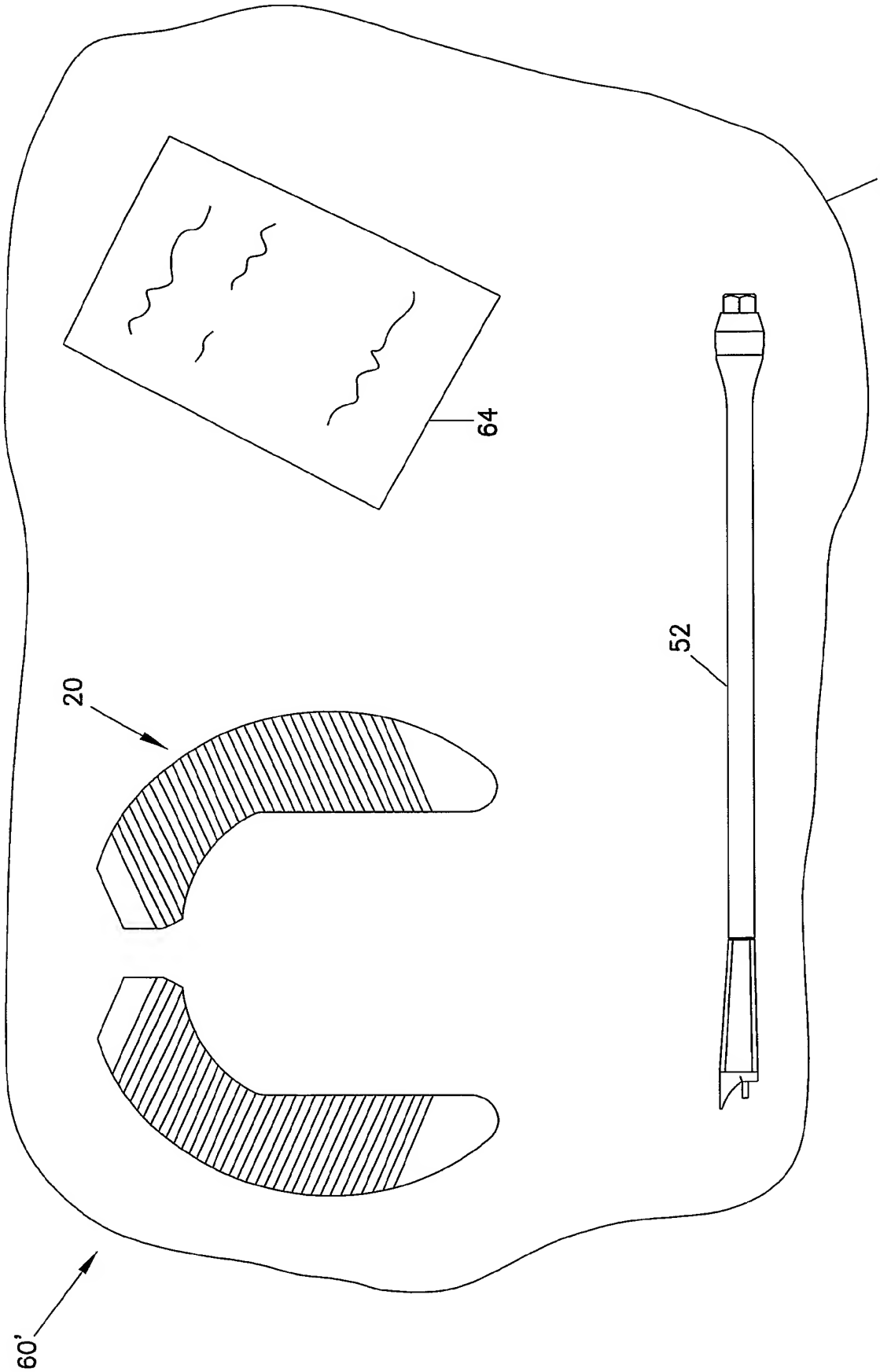


FIG. 8

FIG. 9A

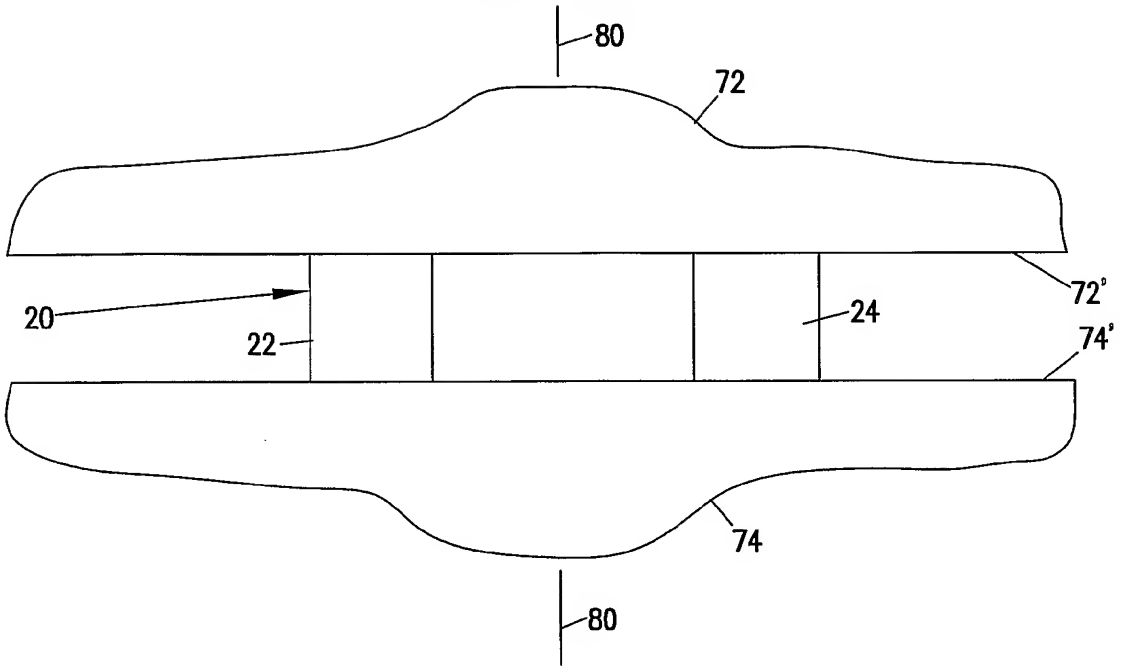
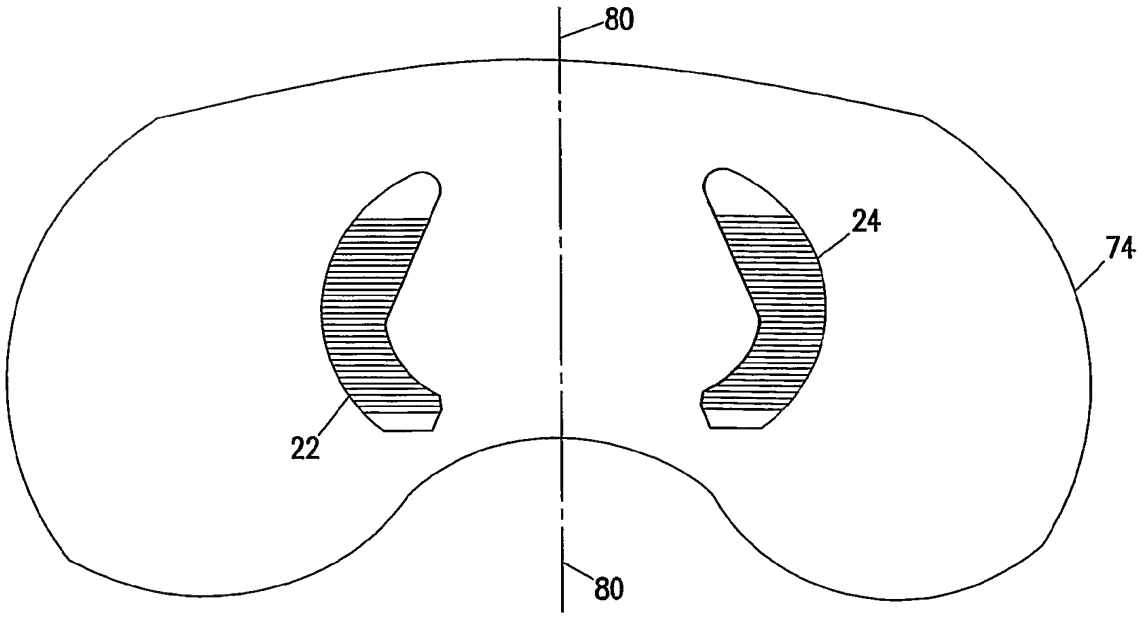


FIG. 9B



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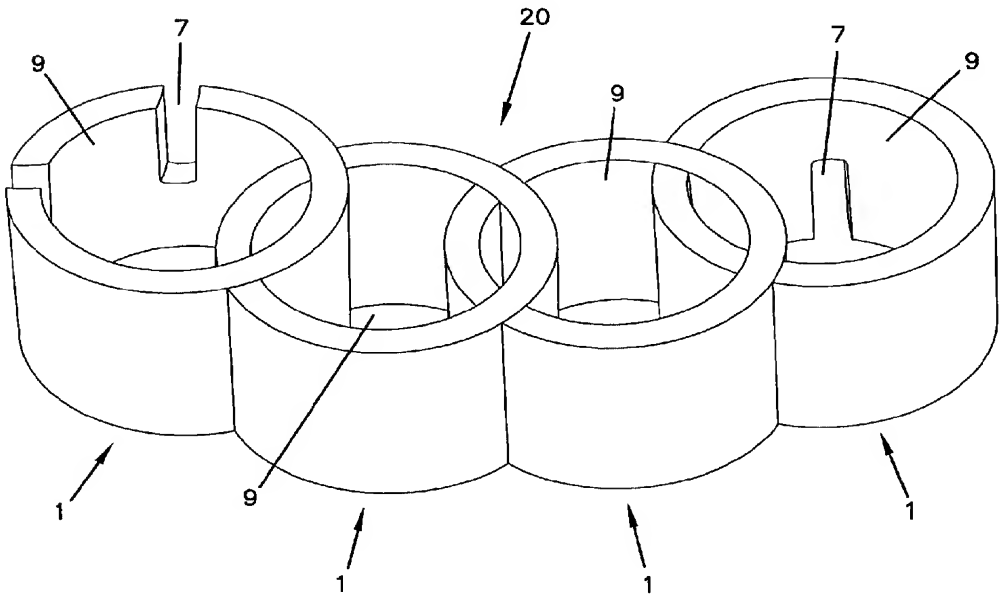

(57) **Abstract:** An implant is disclosed for use in stabilization of one or more bones, for example, adjacent vertebrae. The implant includes two or more coupled structural elements (1). Each structural element includes a first end (2) spaced apart by a side surface (4) from a second end (3). The side surfaces (4) of each structural element include at least one recess (7) and structural elements are coupled by matingly engaging one or more recesses (7).

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MODULAR SPINAL FUSION DEVICE

This application is being filed as a PCT international patent application in the name of Rodney L. Houfburg, a U.S. citizen and resident, on 27 September 2002, designating all countries.

Background

1. Field of the Invention

This invention pertains to a surgical implant for fusing one or more bones. More particularly, the invention relates to a modular implant for use in fusing and/or stabilizing adjacent vertebrae.

2. Description of the Prior Art

Chronic low back pain is one of the most common and perplexing problems facing the field of orthopedic surgery. In addition to patient discomfort, chronic low back pain has severe adverse societal impacts including lost income, possible chronic dependence on drugs or alcohol and public relief programs.

In many cases, low back pain can be avoided by preventing relative motion between spinal vertebrae (commonly referred to as intervertebral stabilization). To abate low back pain, intervention is often directed to stabilizing contiguous vertebrae in the lumbar region of the spine.

Surgical techniques are known for use in spinal stabilization. Surgical techniques seek to rigidly join vertebrae that are separated by a degenerated disk. Ideally, the surgery effectively replaces the vertebra-disk-vertebra combination with a single rigid vertebra. Various surgical techniques have developed which attempt to approach or approximate this ideal.

One technique known in the art is to partially remove a degenerated disk and to insert a bone graft into the void formed by the removed disk. Other techniques involve the use of an implant which, acting alone or in combination with bone fragments, is constructed of non-bone materials (e.g., stainless steel, titanium, ceramics, biodegradable polymers, etc.). An example of such implant is shown in U.S. Pat. No. 4,501,269 to Bagby dated Feb. 26, 1985. In Bagby, a large, cylindrical basket is driven into a hole formed between bones that are to be joined. The basket is

hollow and is filled with bone fragments that are produced during a boring step. Bone-to-bone fusion is achieved through and about the basket. In Bagby, the hole for the Basket is slightly smaller than the diameter of the basket. This structure results in the spreading of the opposing bone segments upon insertion of the basket. This provides initial stabilization. Eventual fusion of the opposing bone segments results from bone growth through and about the basket.

Summary

The invention provides an implant for use in stabilization of one or more bones, for example, adjacent vertebrae. The implant includes two or more coupled structural elements. Each structural element includes a first end spaced apart from a second end. A side surface extends between the first and second ends and includes at least one recess, wherein two or more structural elements are coupled by matingly engaging one or more recesses.

Brief Description of the Figures

Fig. 1A is a top perspective view of a structural element having a plurality of notches extending from a first end.

Fig. 1B is a top perspective view of a curved modular implant according to one embodiment of the invention.

Fig. 2A is a top perspective view of a structural element having a plurality of notches extending from a first end.

Fig. 2B is a top perspective view of a curved modular implant according to another embodiment of the invention.

Fig. 3A is a top perspective view of a structural element having a plurality of notches extending from a first and second end.

Fig. 3B is a top perspective view of a curved modular implant according to another embodiment of the invention.

Fig. 4A is a top perspective view of a structural element having a plurality of notches extending from a first and second end.

Fig. 4B is a top perspective view of a curved modular implant according to another embodiment of the invention.

Fig. 5 is a schematic top view of a modular implant according to one embodiment of the invention.

Fig. 6 is a schematic top view of a modular implant including one or more inserts.

Fig. 7 is a side elevational view of an insert according to the invention.

Fig. 8 is a schematic top view of a modular implant in a clustered configuration.

Fig. 9 is a schematic top view of a modular implant in a curved configuration.

Fig. 10 is a schematic top view of a modular implant in a linear configuration.

Fig. 11 is a schematic side elevational view of a modular implant with structural elements of varying heights to approximate a lordotic angle.

Fig. 12 is a schematic side elevational view of a modular implant including structural elements with non-parallel end surfaces to approximate a lordotic angle.

Fig. 13 is a schematic top view of an alternative structural element.

Fig. 14 is a side elevational view of an alternative structural element.

Fig. 15 is a schematic top view of an alternative modular implant with structural elements having differing shapes in cross section.

Fig. 16 is a schematic top view of an alternative modular implant with structural elements having differing shapes in cross section.

Fig. 17A is a schematic top view of a structural element having a shape of a triangulated cylinder in cross section.

Fig. 17B is a schematic top view of an alternative modular implant with triangulated cylindrical structural elements in a curved configuration.

Fig. 17C is a schematic top view of an alternative modular implant with triangulated cylindrical structural elements in a linear configuration.

Fig. 18 is a photograph showing the location from which cylinders for constructing structural elements may be obtained from human cadaveric tibia.

Fig. 19 is a photograph with a schematic overlay showing the location from which cylinders for constructing structural elements may be obtained from human cadaveric tibia.

Fig. 20 is a top perspective view of an inserter tool.

Fig. 21 is a close-up of the jaws of the inserter tool of Figure 21.

Fig. 22 is a side elevational view of an inserter tool engaging a structural element.

Fig. 23 is a perspective view of the inserter tool of Figure 23, shown from the rear.

Fig. 24 is a close-up of the jaws of an inserter tool engaging a structural element.

Detailed Description

I. Overview:

The invention provides a modular implant for fusing one or more bones. In one embodiment, the modular implant can be used to restore intravertebral disc height and stabilize the vertebral column, while allowing intervertebral (interbody) fusion to occur at the implanted spinal level. Although the disclosure focuses on stabilizing and/or fusing adjacent vertebrae, the invention is not so limited. For example, the invention can be used to fuse other bones, including but not limited to, fractures of or separations in a femur, tibia, humerus, or other long bone. Moreover, the implants are suitable for use with or without additional supporting devices, such as rods, screws, hooks, plates and the like.

The modular implant is formed from two or more structural elements that can be assembled, pre-implantation, in a variety of shapes and sizes to accommodate varying patient anatomies and surgical procedures. Alternatively, in some embodiments, the structural element may be assembled during implantation. The structural elements can be assembled to form modular implants having various sizes and shapes (e.g., curved, straight, clustered, lordotic, etc.). If desired, the modular implant can be implanted in a minimally invasive fashion, from either a posterior, anterior, or lateral approach.

The modular nature of the implant allows for the use of structural elements having an aspect ratio greater than 1. In certain uses, an object having an aspect ratio greater than 1 tends to be "unstable" and prone to tipping over. However, according to one aspect of the invention, two or more such structural elements are coupled together, to form an implant with an aspect ratio of less than or equal to 1. In certain embodiments, the allowable dimensions permit structural elements to be

constructed from a previously underutilized source of cadaveric bone, for example, the human tibia.

Furthermore, although in certain embodiments a connector or a structural element having one or more protrusions can be used in connection with the modular implant of the invention, in one embodiment, the design advantageously does not require the use of a connector or protrusion to engage the structural elements. Thus, in one aspect of the invention, the design eliminates the need for a connector or protrusion, which may create a locus of weakness, enlarge the overall profile of the modular implant, and/or complicate the assembly of the modular implant.

II. Structural Element

One embodiment of a structural element is shown in Figure 1A. As shown in Figure 1A, the structural element 1 includes a first end 2 and a second end 3 spaced apart by an axis A-A of the structural element 1. Generally, a side surface 4 extends between the first end 2 and the second end 3. The side surface 4 of each structural element includes one or more recesses 7 that are configured to matingly engage one or more recesses 7 of another structural element 1 (see FIG. 1B).

In one embodiment, the first 2 and second ends 3 are each load-bearing surfaces that contact the surface of the bone to be fused. For example, when implanted between two adjacent vertebrae in a vertebral column (i.e., one vertebrae is superior to the other), the first end 2 contacts the inferior endplate of a first vertebrae and the second end 3 contacts the superior endplate of the second vertebrae (i.e., the load-bearing surface is the bone-contacting surface). In one embodiment, the first 2 and second 3 end surfaces are substantially parallel (i.e., with one or both end surfaces converging or diverging at an angle of less than about two degrees, more typically less than about one degree), see, for example, Figure 11. Alternatively, the first 2 and second 3 end surfaces may be non-parallel (i.e., with one or both surfaces converging or diverging), see, for example, Figures 12A and 12B. In one embodiment, the first 2 and second 3 end surfaces converge to approximate a lordotic angle α. Typically, the end surfaces 2, 3 converge at an angle between about 0 degrees and about 12 degrees, more typically at an angle between about 2 degrees and about 5 degrees, most typically, at an angle between about 2 degrees and about 3 degrees. If desired, the first 2 and/or second 3 end

surfaces can by textured to improve frictional engagement with the bone surface of the patient. Examples of textured surfaces include, but are not limited to, grooves, ridges, knurls, teeth, cross-cuts, serrations, and the like.

In one embodiment, the structural element includes a lumen or void. For example, the structural element may include an opening 5 in either the first or second end 2, 3, or both. If desired, the opening 5 in one or more structural elements 1 can extend from the first end 2 to the second end 3 of the structural element 1. Each opening 5 has an inner surface 6.

The section of the structural element 1 disposed between the side surface 4 and the inner surface 6 of the opening 5 can be referred to as a wall 12. That is to say, the wall 12 may be defined by the inner surface 6 of at least one opening 5, at least one load-bearing surface 2, 3, and, the side surface 4 of the structural element 1. The thickness of the wall 12 can be varied, typically the wall 12 has a thickness between about 1 mm and about 5 mm, more typically between about 2 mm and about 4 mm, most typically between about 2 mm and about 3 mm. Generally, for a given outer diameter (OD) a structural element with a thicker wall (i.e., between about 3 mm and about 4 mm) provides a modular implant 20 with a smaller cooperative opening 9 (see discussion below). Likewise, a structural element with a thinner wall (i.e., between about 1 mm and about 2 mm) generally provides a modular implant 20 with a larger cooperative opening 9. Compare, for example, Figures 2 and 4.

In one embodiment, one or more recesses 7 extend from the side surface 4 of the structural element 1 to the inner surface 6 of the opening 5 in the structural element 1. The recesses 7 each have an inner surface 13. In one embodiment, the recesses 7 extend from the first 2 or second 3 end, or both, in a direction parallel to the axis A-A of the structural element 1. Recesses 7 that extend from the first 2 or second 3 end (or both) also can be referred to as notches. The portion of the wall 12 of the structural element 1 located between two recesses 7 can be referred to as a column C. The walls of inner surface 13 of the recess 7 are substantially parallel. In an alternative embodiment, the walls of the inner surface 13 of the recess are converging to improve the strength/tightness of fit between the coupled structural elements 1.

In some cases, it may be desirable to form a structural element 1 having a plurality of evenly spaced recesses 7. In one embodiment, the plurality of recesses 7 are evenly spaced around the perimeter (p). In another embodiment, the recesses 7 are not evenly spaced around the perimeter (p). In one embodiment, the recesses 7 are configured as notches that are not evenly spaced around the perimeter (p) of the structural element 2. In this embodiment, the structural element 1 includes recesses 7 that define at least one minor column C'. As used herein, the term "minor column" C' refers to a column whose radial arc is smaller than that of at least one other column C of the structural element 1. For example, in the embodiment shown in Figure 1A, the structural element 1 includes four recesses 7 that extend from a first end 2 to define four columns C. The recesses 7 are spaced such that they define at least one minor column C'. In one embodiment, the minor column C' is smaller than the other columns C. The notches 7 can all extend from one side surface, as shown in Figures 1A and 2A, or the notches 7 can extend from both side surfaces, as shown in Figures 3A and 4A. In one embodiment, the modular implant 20 may include one or more "end" structural elements 1 that include recesses 7 that do not mate with recesses 7 of another structural element 1 (see, for example, Figures 2B, 3B and 4B). In an alternative embodiment, specialized "end" structural elements 1 can be provided, such that the resulting modular implant 20 does not include an "end" structural element with "unmated" recesses 7 (see, for example, Figure 1B)

In some cases, it may be desirable to provide one or more recesses 7 with a textured inner surface 13 to enhance frictional engagement between the recesses 7 when the structural elements 1 are coupled. Examples of suitable textured surfaces include grooves, knurls, etc. Specifically oriented patterns can be designed to enhance "locking" between structural elements 1.

The structural element 1 can have any suitable shape (see, for example, Figures 1-18). In one embodiment, at least one structural element has a substantially round shape in cross-section, for example, the structural element 1 may be circular, oval, or elliptical in cross-section. The term "rounded" refers to a structural element 1 with at least one arcuate surface. Therefore, the term "rounded" also includes structural elements 1 that have the shape of a "truncated circle" (or "truncated cylinder") in cross section. As used herein, the term "truncated circle" refers to a shape formed by cutting one or more flat surfaces into the circumference of a circle.

For example, a "truncated circle" can be a shape formed by cutting a circle in half, to form a semi-circle. In another example, a "truncated circle" is a "triangulated circle." As used herein, the term "triangulated circle" refers to a shape that is created by cutting three flat surfaces of a circle. Generally, a "triangulated circle" has a shape of a triangle, but the angles (or corners) are rounded. In another embodiment, the structural element has a shape in cross-section that is angled, for example, the structural element 1 may be square, triangular, rectangular, trapezoidal, or a rhombus in cross section. As used herein, the term "angled" refers to a shape formed by the intersection of two planes. Included within the scope of this invention are structural elements having a shape that is both "rounded" and "angled" in cross section. In one embodiment, the structural element 1 is substantially in the shape of a cylinder (see, for example, Figures 1-4). In another embodiment, the structural element 1 is in the shape of a triangulated cylinder (see, for example, Figure 17A-C).

The structural element 1 can be any size suitable for the site of implantation. For example, for use in spinal fusion, a structural element 1 can have a major width ranging between about 7 mm to about 28 mm and a height between about 5 mm to about 20 mm. The size of the structural element 1 also may vary depending on the desired surgical procedure and patient anatomy. Generally, a structural element 1 for use in constructing a modular implant 20 for fusing cervical vertebrae of an adult human patient will have a major width between about 5 mm to about 10 mm and a height between about 5 mm to about 9 mm. In contrast, a structural element 1 for use in constructing a modular implant 20 for fusing lumbar vertebrae of an adult human patient will generally have a major width between about 7 mm to about 28 mm and a height between about 8 mm to about 20 mm.

The "major width" of a structural element 1 can be determined by calculating the length of a vector (V) extending in a direction perpendicular from a first point on the perimeter (p) of the side surface of the structural element to a second point on the perimeter (p) of the side surface. The length of the vector (V) having the longest length is the "major width" of the structural element 1. Generally, for a cylindrical structural element 1, the "major width" corresponds to the outer diameter (OD) of the cylinder. For a structural element having an irregular shape in cross section (e.g., an oval, rectangular, triangulated cylinder, trapezoid, or other irregular shape), the "major width" can be determined as described above.

The "height" of a structural element 1 can be determined by measuring the distance between the first 2 and second 3 end surfaces. If the first 2 and second 3 end surfaces are not parallel, the greatest distance therebetween is used to assess the "height" of the structural element 1.

The structural element 1 can be constructed from any suitable biocompatible material, such as bone, metal, ceramic, plastic, and combinations thereof. Suitable bone materials include materials from human (including both allograft and autograft) and animal sources (e.g., xenograft, for example, bovine sources), typically from long bones such as the tibia, femur, and humerus. Suitable plastics include polyetheretherketone (PEEK). The plastic can be used with or without carbon fiber (i.e., to enhance structural strength). Suitable metals include titanium and titanium alloys (such as Ti 6AI 4V), memory metals such as Nitinol™, stainless steels (such as 306L) and porous metals. If desired, the structural element can be constructed from an osteoinductive material, osteoconductive material, radio opaque material, radiolucent material, and combinations thereof.

In one embodiment, the structural element 1 is constructed from a bone material, for example, from a tibial source (such as a human tibial source, typically, a human cadaveric source). Although the tibia is the second largest bone of the human skeleton, it is generally not used in fusion implants due to the limited dimensions of cortical bone that can be harvested. However, because the structural elements 1 of the invention are coupled prior to implantation, an expanded range of sources of cortical bone, such as the tibia, now can be used.

FIG. 18 shows a possible location from which cortical bone can be harvested from a human tibia (T). As shown in Figure 18, the shaft of the tibia is approximately triangular in transverse section with medial (M), lateral (L) and posterior (P) surfaces formed from cortical bone. When viewed in cross section, the three surfaces intersect to define a medullary cavity. The medial (M) and lateral (L) surfaces intersect at an anterior (A) junction, which generally has a greater dimension than the medial (M), lateral (L) and posterior (P) surfaces. Thus, it may be desirable to harvest cortical bone from the tibia at the anterior (A) junction. In one technique, cylinders of cortical bone are machined from the anterior (A) junction of the tibia. If desired, "triangulated" cylinders can be machined from the anterior (A) junction, as shown in Figure 19. It may be desirable to machine

"triangulated" cylinders as certain segments of a long bone (e.g., a tibia) have an anterior junction of insufficient dimensions to provide a completely round structural element. Triangulated cylinders offer the advantage of a larger cooperative opening and alternative final implant geometries when coupled together.

Generally, when the structural element 1 is constructed from bone material obtained from a tibial source, the structural element has a major width of less than about 11 mm. Typically, a structural element 1 harvested from a human tibia will have a major width between about 8 mm and about 11 mm, more typically between about 8 mm and about 10 mm, most typically between about 8 mm and about 9 mm, particularly if the bone is harvested from the anterior junction of the tibia.

II. Modular Implant

The invention also provides a modular implant 20 constructed by coupling two or more of the structural elements 1, described above. Advantageously, in one embodiment, the structural elements 1 can be coupled, prior to implantation, to form a "customized" modular implant 20 designed for the anatomy of a particular patient and/or a particular surgical procedure.

Modular implants 20 having a variety of shapes and sizes can be constructed, depending on the number, orientation and assembly of the structural elements 1. Typically, the modular implant includes between 2 and 10 structural elements 1 that are coupled together. Modular implants 20 having varying heights also can be created, using structural elements 1 having different heights. For example, a modular implant 20 suitable for use in fusing lumbar vertebrae may be assembled using structural elements 1 having a height between about 8 mm and about 20 mm. Alternatively, a modular implant 20 suitable for use in fusing cervical vertebrae may be assembled using structural elements 1 having a height between about 5 mm and about 9 mm. A "stepped" modular implant 20 also can be created for maintaining a lordotic angle by assembling two or more structural elements 1 of varying heights (see, for example, Figure 11). If desired, a "lordotic" modular implant 20 can be assembled using structural elements 1 having first 2 and second 3 end surfaces that are angled with respect to each other (see, for example, Figures 12A-D). In one embodiment, a modular implant 20 includes at least one structural element 1 that has a height that is different than the height of at least one other structural element 1. In

another embodiment, a plurality of structural elements 1 having various heights are coupled to form a modular implant. Additionally, one or more structural elements 1 constructed from different materials (e.g., PEEK, bone, metals, or ceramic) can be combined in a single modular implant 20. For example, metal and bone structural elements 1 can be coupled to create a modular implant 20 having the enhanced strength characteristics of metal and the biological advantages of bone (e.g., creeping substitution, osteoconductivity, etc.). In one embodiment, at least one structural element 1 is constructed from a material that is different than at least one other structural element 1. One or more structural elements 1 having differing shapes in cross-section also can be coupled together to form a modular implant 20 (see, for example, Figures 15 and 16). In one embodiment, at least one structural element has a shape in cross-section that is different from at least one other structural element.

Generally, one or more recesses 7 extend from the side surface 4 of the structural element to the inner surface 6 of the opening 5 in the structural element. Typically, the recess 7 has a width that corresponds to a width of the wall 12 of the structural element 1 it is configured to matingly engage. Alternatively, the recess 7 width may be somewhat smaller than the wall 12 width (e.g., to provide a "press-fit" coupling of the structural elements). In a further alternative embodiment, the recess 7 width may be somewhat larger than the wall 12 width (e.g., to provide a degree of "play" and/or to accommodate the inclusion of a bonding agent or in the coupling of the structural elements).

As described above, the first 2, second 3, or both, end surfaces (e.g., the bone-contacting surface) can be smooth or may include a textured pattern to enhance frictional engagement with the bone surface. The textured pattern of the structural elements may align or be unidirectional when the structural elements 1 are coupled, or the textured pattern of the various structural elements 1 may run in different directions. In an alternative embodiment, the side surfaces of the structural elements may function as the bone-contacting surface, and thus may include similar textured patterns.

The structural elements 1 of the invention can be assembled to form modular implants 20 having various shapes. For example, the structural elements 1 can be assembled to form clustered, curved, and/or linear implants (see, Figures 8, 9, and

10, respectively). As used herein, the term "linear" refers to a modular implant 20 in which each structural element 1 is adjacent to no more than two other structural elements, and wherein a line connecting the axes A-A of the structural elements 1 (see e.g., line a'-a' of the modular implant in FIG. 10) is generally linear. Similarly, the term "curved" refers to a modular implant 20 in which each structural element 1 is adjacent to no more than two other structural elements, wherein a line connecting the axes A-A of the structural elements 1 (see e.g., line a'-a' of the modular implant of FIG. 9) is curved. The curvature can be unidirectional, like the letter "C"; bi-directional, like the letter "S"; or even multi-directional (e.g., sinusoidal). The modular implants may also be assembled both into shapes including linear and curves sections (e.g., a "U" shaped modular implant). The radius of curvature can be altered by changing the location and/or orientation of the recesses 7 around the perimeter (p) of the structural element 1. Generally, a curved modular implant 20 will tend to have more stability in a direction transverse to the axis a'-a' than a linear modular implant 20. Suitable radii of curvature include those between about 18 and about 50.

In one embodiment, the same set of structural elements 1 can be used to create a linear or a curved modular implant depending upon the orientation of the recesses 7 of the structural element 1. For example, each structural element may have a perimeter (p) and a plurality of recesses 7 that are not evenly spaced around the perimeter (p), such that the recesses 7 define at least one minor column C', which is smaller than the other columns. To assemble a curved implant 20, the minor column C' is aligned towards the inside of the curve. In contrast, to assemble a linear implant 20, the minor column C' is placed on alternating sides of the implant. (see, Figures 9 and 10, respectively).

If desired, the length of a modular implant 20 resulting from assembly of a specified number of structural elements 1 can be varied by altering the spacing between the recesses. For example, a curved implant constructed from five structural elements 1, each having an outer diameter (OD) of 8 mm can have a length (X) of 22 mm. However, if a curved implant is constructed from five structural elements 1, each having an outer diameter (OD) of 8 mm spacing, but the spacing between the recesses 7 is increased, the curved implant can have a length (X) of 28 mm. (See, Figure 5).

Generally, the modular implants 20 of the invention tend to be stable, even when the structural elements 1 may be unstable (e.g., prone to tipping). That is because, in certain embodiments, the modular implant 20 has an aspect ratio less than or equal to one. In alternative embodiments, the modular implant includes or a radius of curvature that improves stability, even when individual structural elements 1 having an aspect ratio of greater than one are used. Thus, the structural elements 1 of the invention can be constructed using sources that may not otherwise be suitable, for example, tibial bone material (see discussion above) and/or be used in a wider array of indications (e.g., cervical and lumbar fusion procedures) than previously known.

As used herein, the term "aspect ratio" of a structural element refers to the ratio of the height of a structural element to the width of at least one load-bearing surface of the structural element. The width of a structural element having a circular cross section can be determined by calculating the diameter of the circle. For a structural element having an irregular shape in cross section (e.g., oval; rectangular, including square; triangle; trapezoid; or other irregular shape), the width the of the load-bearing surface can be calculated by calculating the length of a vector extending in a direction perpendicular from a first point on the perimeter of the load-bearing surface to a second point on the perimeter of the load-bearing surface. The vector having the shortest length is used as the width (the "minor width") of the load-bearing surface when calculating the aspect ratio. For structural elements having load-bearing surfaces that are not parallel (e.g., a structural element approximating a lordotic angle), the greatest height of the element is used to calculate the aspect ratio. In one embodiment of the invention, the modular implant 20 includes at least one structural element 1 that has an aspect ratio that is different than the aspect ratio of at least one other structural element 1. In another embodiment, at least one structural element 1 has an aspect ratio of greater than one, wherein the modular implant 20 has an aspect ratio that is less than or equal to one.

In one embodiment, when the structural elements 1 are coupled together to form a modular implant 20, the structural elements are in an "overlapping" configuration. As used herein, the term "overlapping" means that a width of the modular implant is less than the sum of the width of the structural elements 1. Generally, this means that the axes of the structural elements are offset, while the

walls of the structural elements 1 interlock. In one embodiment, both the first 2 and second 3 end surfaces of each structural element 1 remain bone-contacting surfaces, even when the structural elements are interlocked. Typically, in this embodiment, the axes of the structural elements 1 are parallel. In one embodiment, when in the "overlapping" configuration, the inner surface 6 of at least one structural element 1 faces the inner surface 6 of at least one another structural element 1.

Although not necessary, a biocompatible bonding agent can be used to secure the coupling of the structural elements 1, if desired. Examples of suitable biocompatible bonding agents include polymethylmethacrylate (PMMA), and fibrin glue. Alternatively, or additionally, the modular implant 20 can be hydrated (for example, by immersing the implant 20 in a saline solution at a temperature between about 18°C and about 25°C, for between about 30 minutes and about 45 minutes) to cause the coupled structural elements 20 to swell and increase the mechanical locking force between them. Hydration is particularly suitable when the modular implant 20 is assembled from structural elements 1 constructed from a hydratable material, for example, a bone material.

In one embodiment, the modular implant 20 includes a biologically active agent, such as a bone growth enhancing material or an antibiotic. As used herein, the term "biologically active agent" refers to, without limitation, physiologically or pharmacologically active substances that act locally or systemically in the body. Of particular suitability for this invention are biologically active agents that are osteoinductive or osteoconductive. Examples of materials that enhance bone growth and/or fusion include, but are not limited to, bone or bone substitute products such as human growth factors, bone morphogeneic proteins (BMP), cancellous bone, autograft bone, allograft bone, etc. Examples of antibiotics include antimicrobials and antibacterials.

As described above, one or more structural elements 1 may include a lumen or void. For example, the structural element may include at least one opening 5 in at least end surface 2, 3, wherein each opening 5 has an inner surface 6. If desired, the biologically active agent can be placed within the void or opening 5.

In another embodiment, the implant 20 includes one or more cooperative openings 9 defined by the inner surface 6 of an opening 5 in a first structural element 1 and a side surface 4 of an overlapping structural element 1. If desired,

one or more inserts 11 can be configured to be received within a cooperative opening 12 of the implant 20 (see, for example, Figures 6 and 7). The insert 11 can be constructed from any suitable material. In one embodiment, the insert 11 includes a biologically active agent. As shown in Figure 17B-C, structural elements 1 formed as a "triangulated cylinder" tend to increase the size of the cooperative opening 9 in the modular implant 20.

III. Method

The invention also includes a method for fusing one or more bones. Generally, the method includes obtaining or providing two or more structural elements 1, described above. The recesses of the structural elements 1 are engaged to form a modular implant 20, which is then inserted between the bones to provide stability and/or enhance fusion. Alternatively, the structural elements may be engaged during and/or at the site of implantation.

In one embodiment, the implant 20 of the invention is used to facilitate fusion of adjacent vertebrae, including cervical, thoracic, and lumbar vertebrae. The assembled implant 20 can be inserted into the disc space via an anterior approach, posterior, or lateral approach. Those of skill in the art are familiar with methods for implanting spinal fusion devices from these approaches, including open, and minimally invasive, for example, laproscopic procedures. In some embodiments, it may be desirable to assemble the structural elements 1 to form a clustered implant 20 when used in connection with an anterior approach. In other embodiments, when used in connection with a posterior approach, it may be desirable to assemble the structural elements 1 to form a curved or linear implant 20.

According to the invention, the medical practitioner can assemble the structural elements 1 to form a modular implant 20 suitable for the particular anatomy of the patient or surgical procedure used.

IV. Inserter tool

The invention also includes an inserter tool 50 useful for handling and/or implanting the modular implant 20, described above. The inserter tool 50 includes a pair of intersecting arms and a common axis interconnecting the intersecting arms wherein the arms are capable of rotating around the common axis (Figure 20).

The inserter tool 50 includes first 51 and second 52 arms. The first arm 51 includes a first proximal shaft 53 and a first distal shaft 54. A first moveable head 55 is rotatably connected to the first distal shaft 54 at a first axis 56. The second arm 52 includes a second proximal shaft 57 and a second distal shaft 58. A second moveable head 59 is rotatably connected to the second distal shaft 58 at a second axis 60 and connected to the first movable head 55 at a third axis 61. Thus, the first 51 and second 52 arms are pivotally connected at a fourth axis 62 and are capable of rotating around the fourth axis 62.

If desired, the inserter tool can include a biasing member configured to hold the first proximal shaft 53 and second proximal shaft 57 in a spaced apart relationship. The inserter tool 50 also may include a base member 63 attached to the first 51 and second 52 arms at the third 61 and fourth 62 axes.

Generally, the first 55 and second 59 moveable heads span a width (W) when engaging the modular implant 20. As used herein, the "width" spanned by the first moveable head 55 and second moveable head 59 refers to the distance between the first exterior surface 66 of the first moveable head 55 and the second exterior surface 67 of the second moveable head 59. Preferably, the width (W) spanned by the first 55 and second 59 moveable heads when engaging the modular implant 20 is no greater than a major width of at least one structural element 1 of the implant 20. (Figure 21)

The clamp can be constructed using any suitable material, including metal, such as stainless steel or titanium or plastics such as injection-molded plastic.

In use, the arms 51, 52 of the inserter tool 50 are rotated apart and a modular implant 20 is positioned between the first 55 and second 59 moveable head. The arms 51, 52 of the inserter tool 50 are then rotated towards one another to engage the modular implant 20. In one embodiment, the first moveable head 55 includes a first projection 64 configured to engage a first recess 7 of the modular implant 20. Likewise, the second moveable head 59 includes a second projection 65 configured to engage a second recess 7 of the modular implant 20 (Figures 22-24). Alternatively, the first 55 and second 59 moveable heads are configured to frictionally engage the side surface 4 of at least one structural element 1 of the modular implant 20.

Having disclosed the invention, modifications and equivalents of the disclosed concepts may occur to one skilled in the art. It is intended that the scope of the present invention not be limited to the specific embodiment disclosed, but shall include such modifications and equivalents.

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WHAT IS CLAIMED IS:

1. A modular implant, comprising:

- a first and a second structural element, each including
- a first end spaced apart from a second end by a side surface; and
- one or more recesses in the side surface,

wherein the first and second structural elements are coupled by matingly engaging one or more recesses.

2. The implant according to claim 1, wherein at least one structural element comprises a wall defined by an inner surface of at least one opening, at least one load-bearing surface, and a side surface of the structural element.

3. The implant according to claim 1, wherein at least one structural element has a shape in cross-section that is rounded.

4. The implant according to claim 3, wherein the rounded shape in cross-section is selected from a circle, an oval, an ellipse, and a triangulated circle.

5. The implant according to claim 1, wherein at least one structural element has a shape in cross-section that is different from at least one other structural element.

6. The implant according to claim 1, wherein each structural element has a perimeter, wherein at least one structural element has a plurality of recesses defined in at least one load-bearing surface.

7. The implant according to claim 1, wherein at least one structural element is constructed from a material selected from bone, metal, ceramic, plastic, and combinations thereof.

8. The implant according to claim 1, comprising a plurality of structural elements having varied heights, such that the structural elements, when in an

overlapping configuration, approximate a lordotic angle between at least two adjacent vertebrae.

9. The implant according to claim 1, further comprising first and second load bearing surfaces parallel to one another.

10. The implant according to claim 1, further comprising bone growth enhancing material.

11. The implant according to claim 1, wherein an inner surface of at least one structural element faces an inner surface of at least one other structural element when the structural elements are in an overlapping configuration.

12. The implant according to claim 1, wherein the recesses are notches extending within the side surface from the first end, wherein the first and second structural elements are coupled by matingly engaging one or more notches.

13. The implant according to claim 12, wherein at least one structural element is substantially cylindrical in shape, and at least on of the structural elements includes a void.

14. The implant according to claim 1, wherein the first and second structural elements each includes a sidewall extending between the first and second ends, wherein the sidewalls of the first and second structural elements overlap when the first and second structural elements are coupled.

15. The implant according to claim 1, wherein at least one structural element has an aspect ratio of greater than 1, and the modular implant has an aspect ratio less than or equal to 1.

16. The implant according to claim 1, wherein at least one structural element has a height between about 5 mm and about 20 mm and a width between about 7 and about 28 mm.

17. The implant according to claim 1, wherein the recess in the first structural element is configured for mating engagement with a complimentary recess in the second structural element.

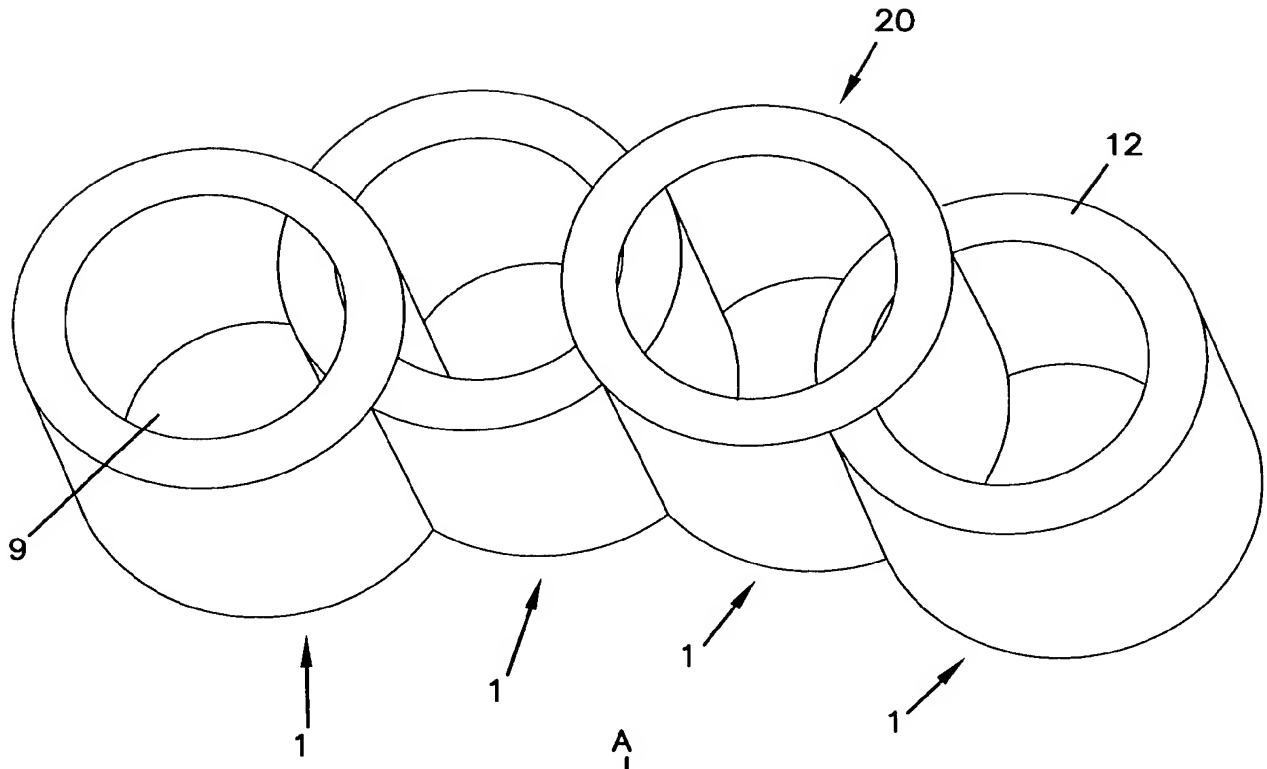
18. A method for manufacturing a modular implant, the method comprising:

- cutting one or more structural elements from a segment of bone, wherein the structural elements each include first and second ends spaced apart by a side surface;
- forming one or more recesses in the side surface; and
- coupling two or more structural elements by matingly engaging recesses of one structural element with recesses of another structural element.

19. The method of claim 18, wherein cutting the structural elements from a segment of bone involves forming the elements such that they have a shape in cross-section that is rounded.

20. The method of claim 18, wherein forming the recesses involves creating notches extending within the side surface from the first end.

FIG. 1B



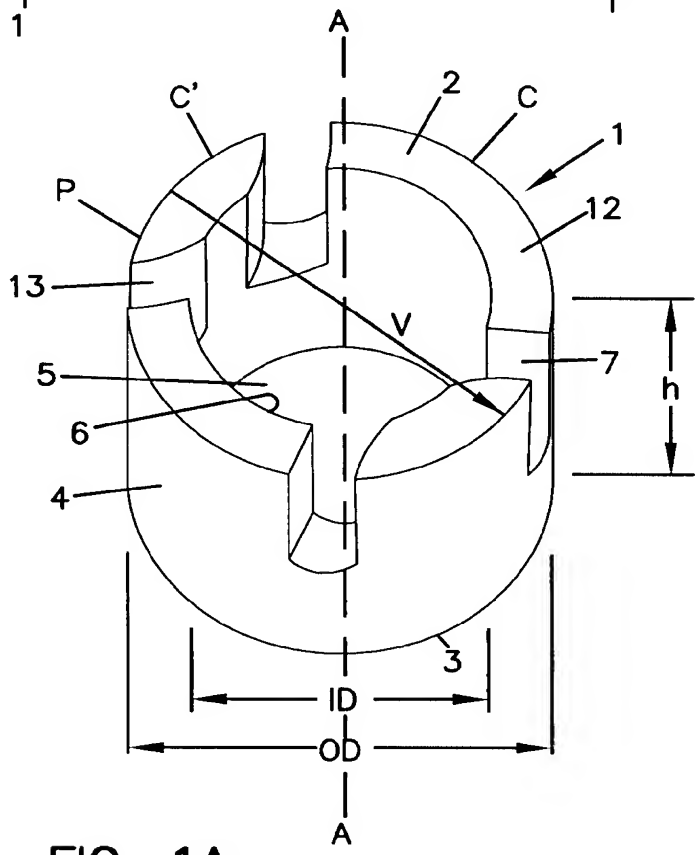
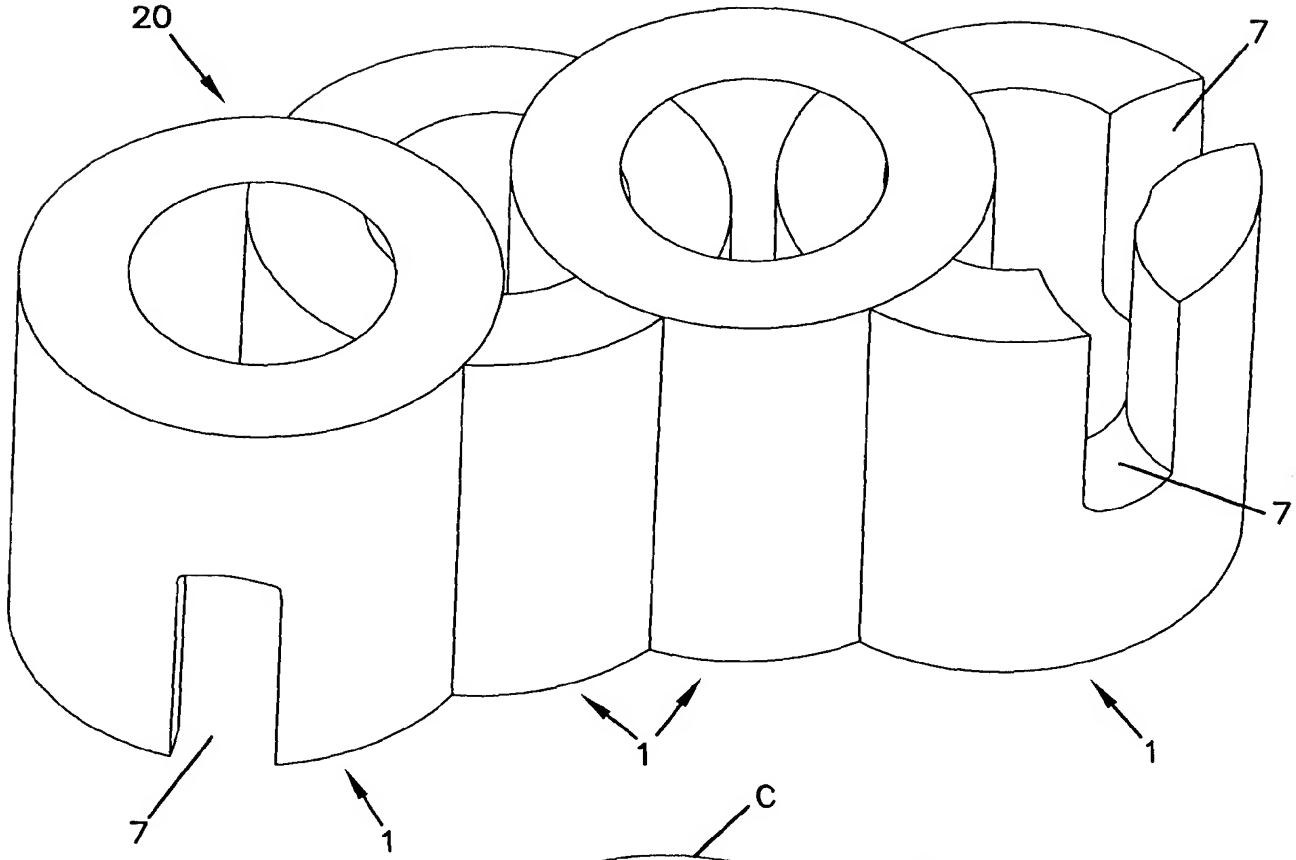


FIG. 1A

FIG. 2B



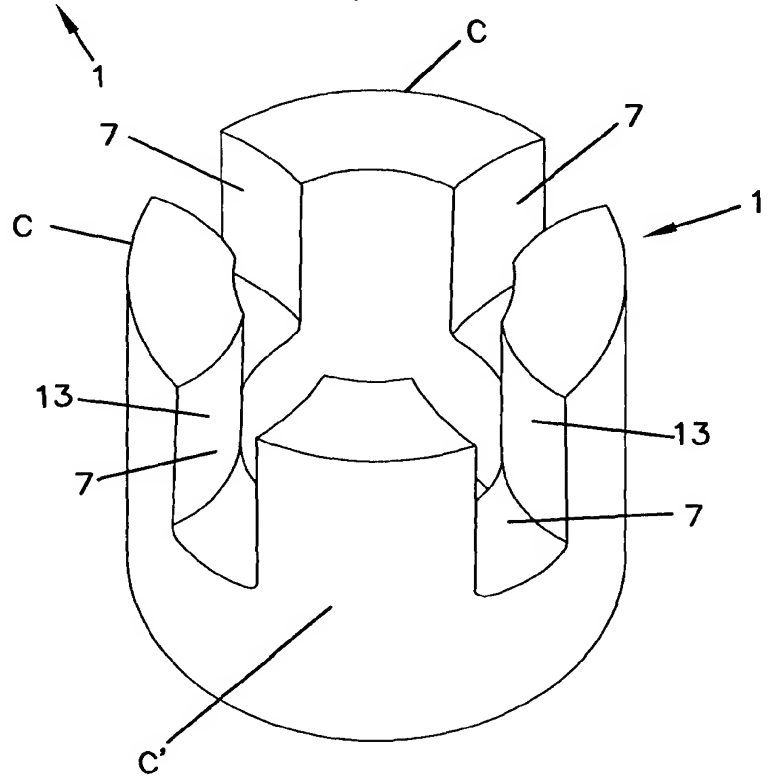
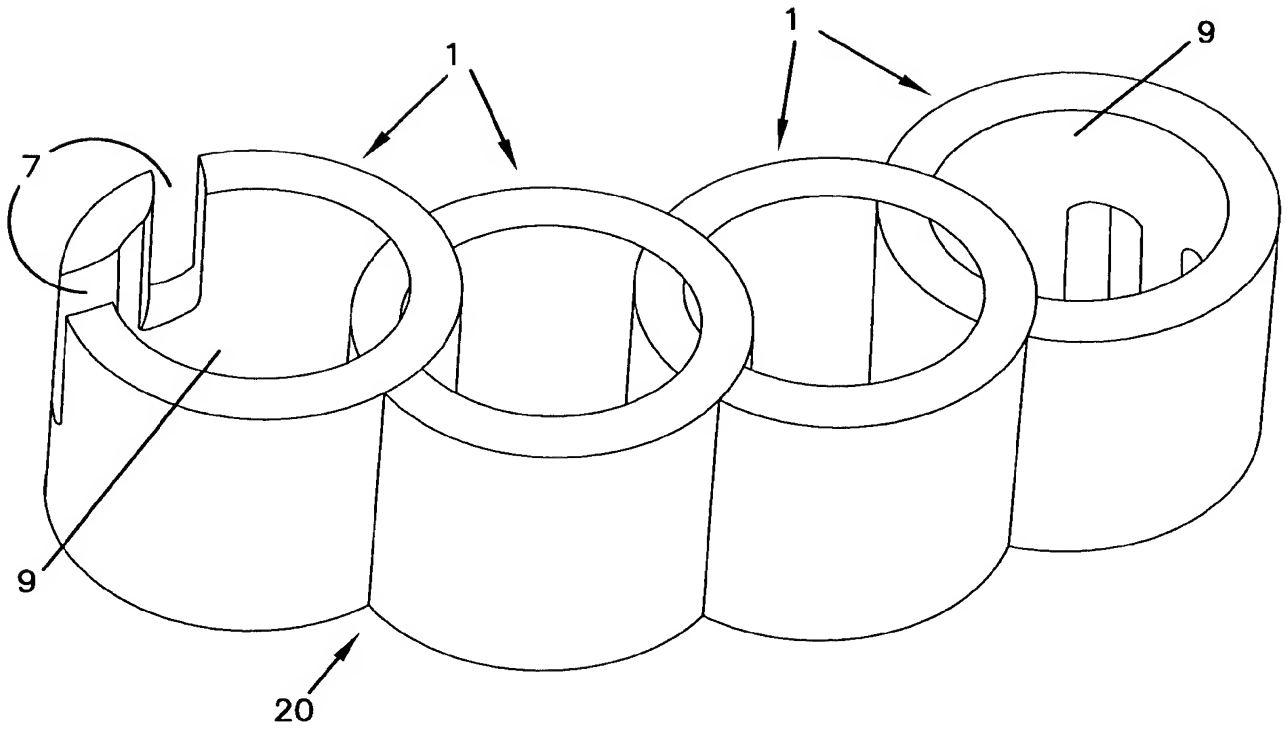


FIG. 2A

FIG. 3B



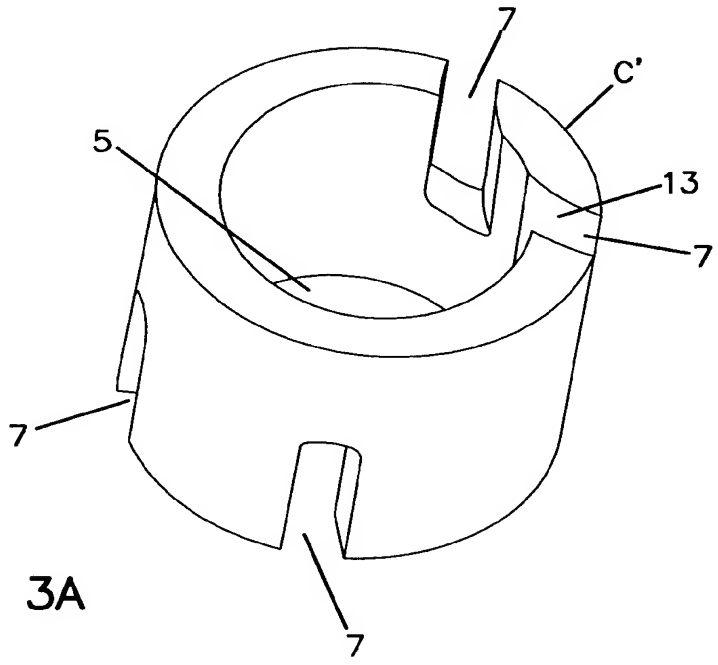


FIG. 3A

FIG. 4B

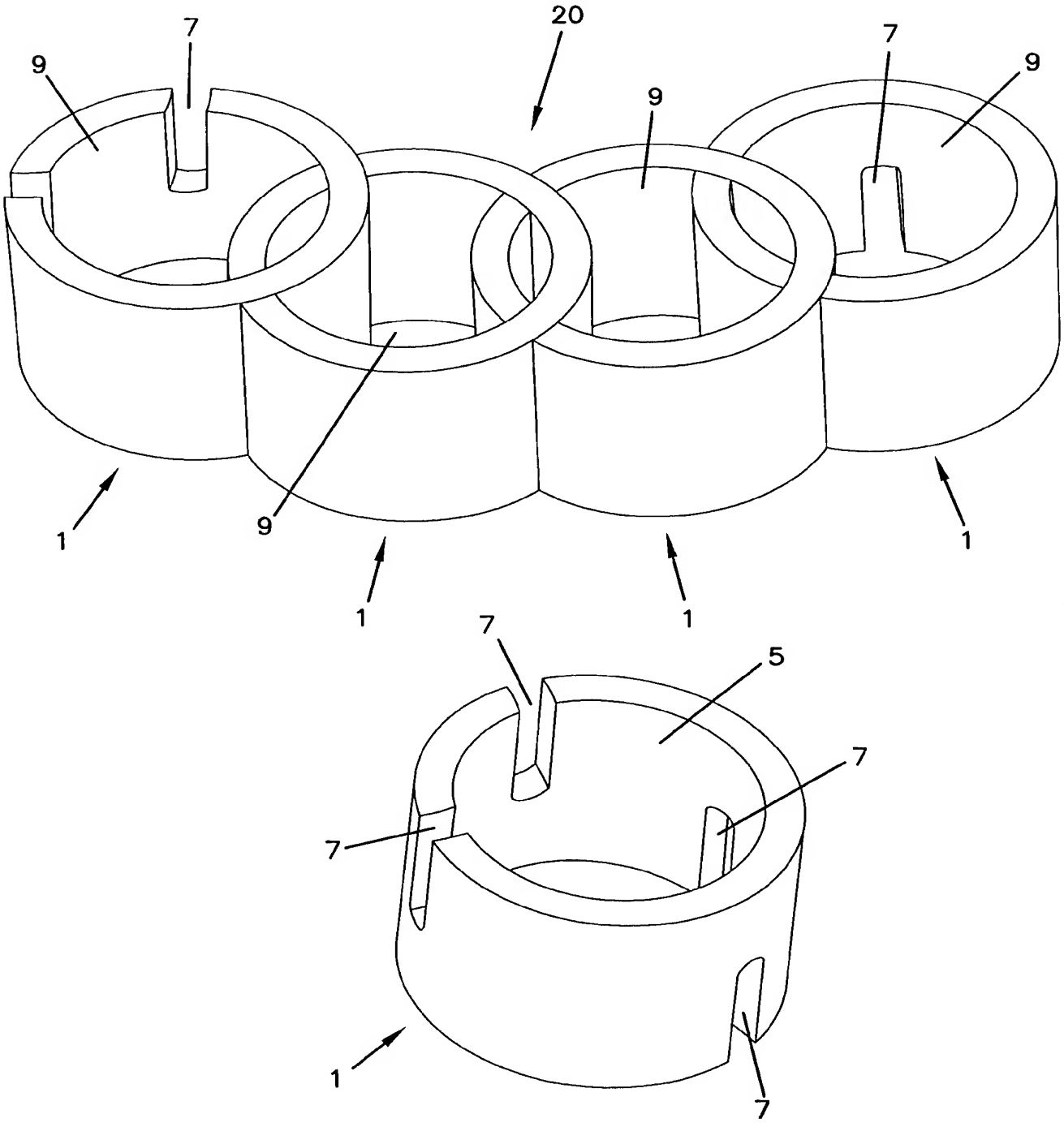


FIG. 4A

FIG. 5

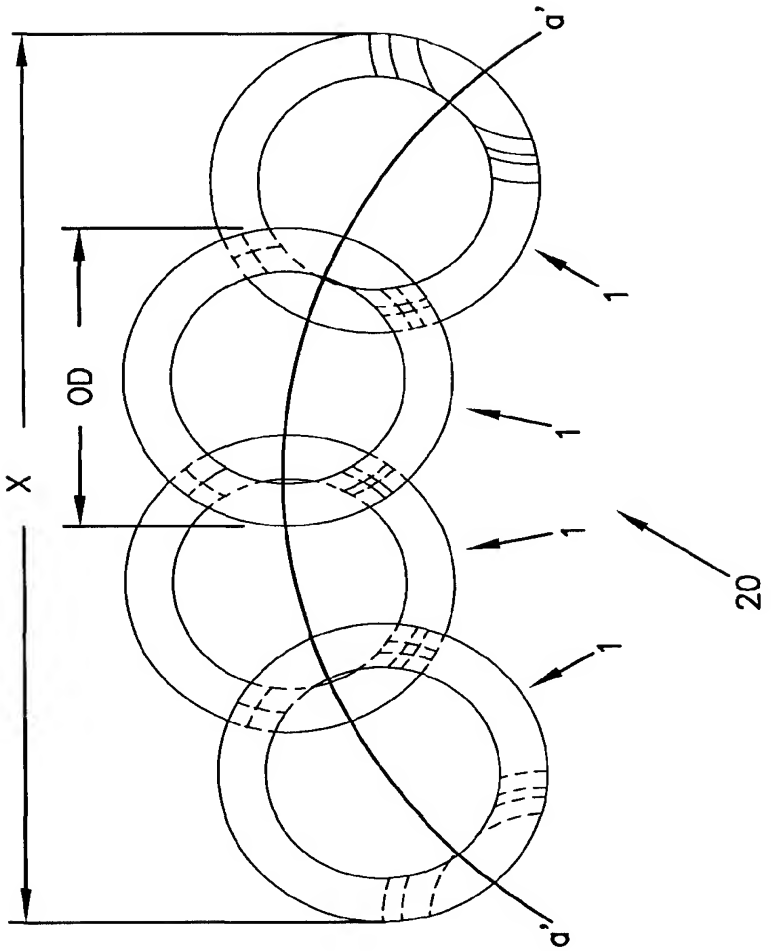
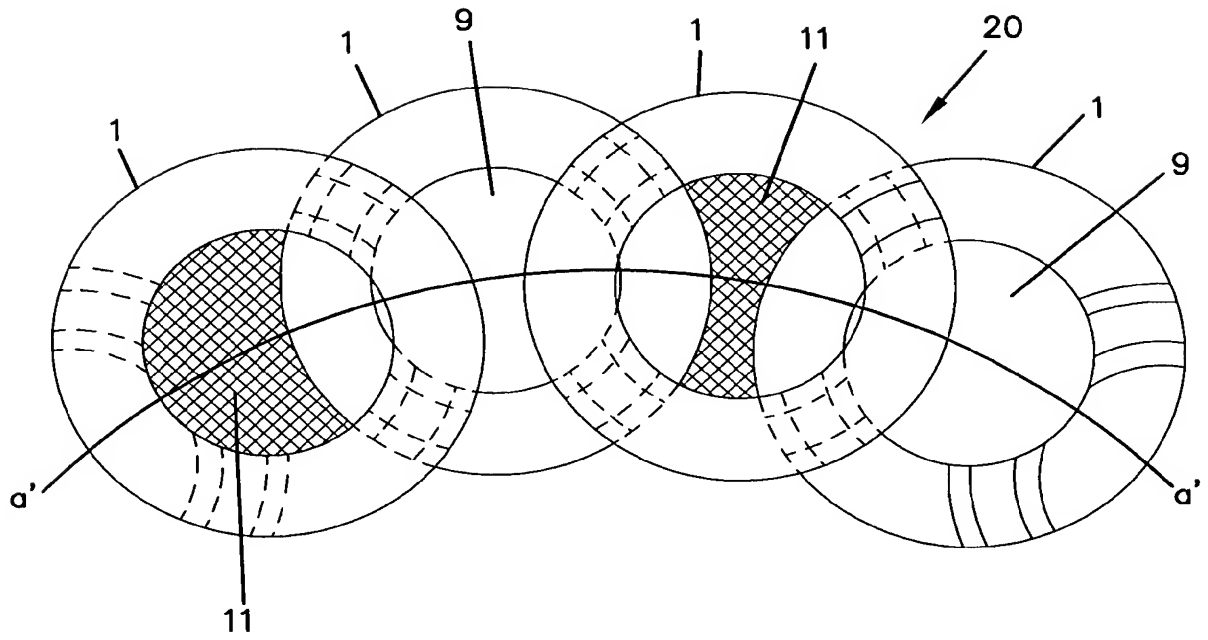


FIG. 6



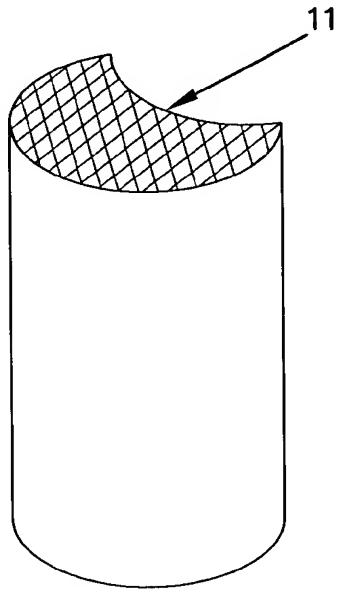
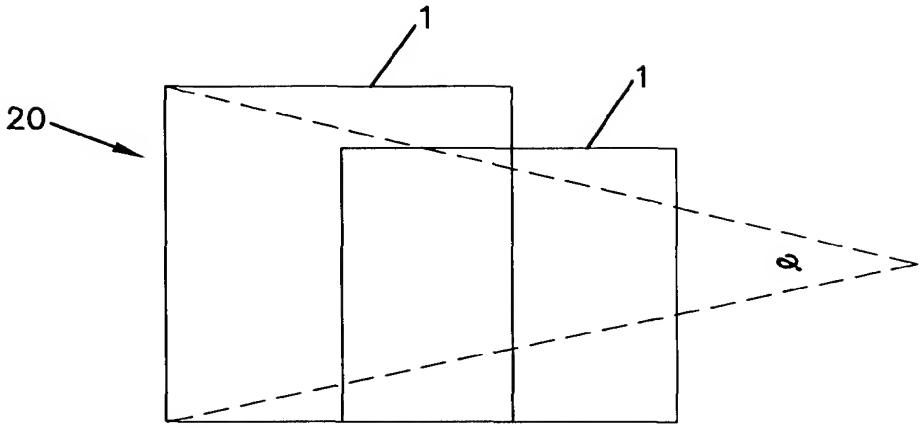


FIG. 7

FIG. 12



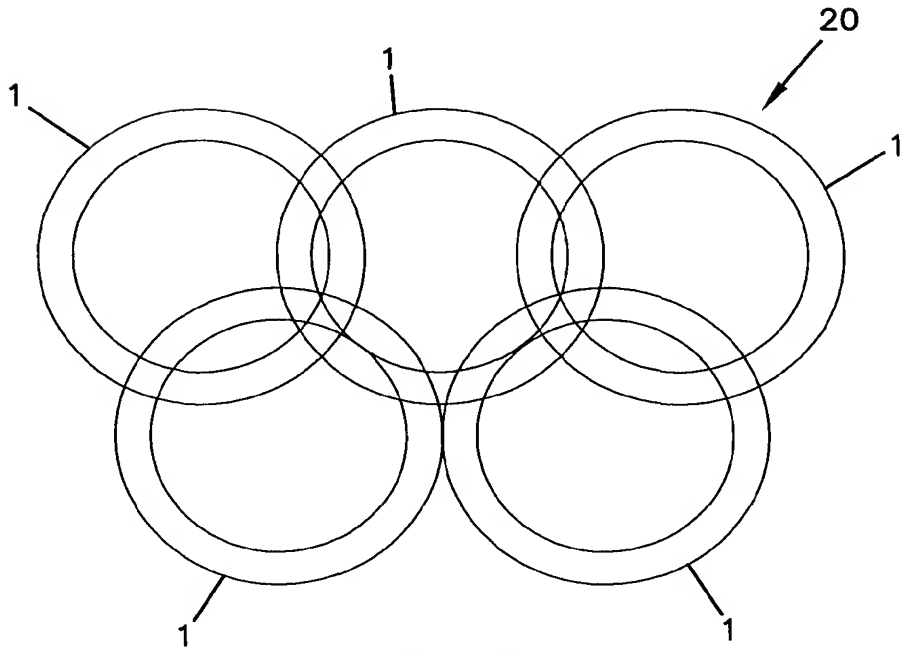


FIG. 8

FIG. 11

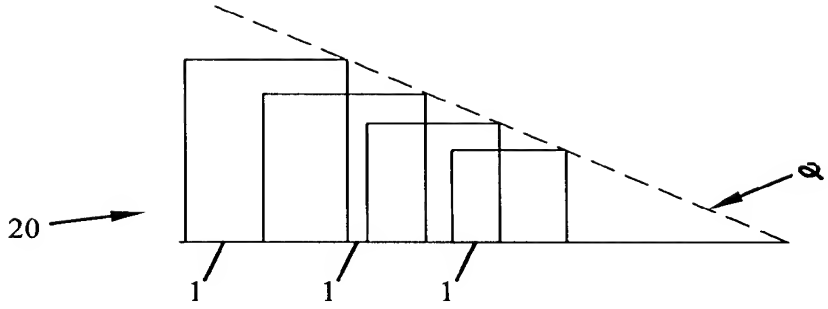
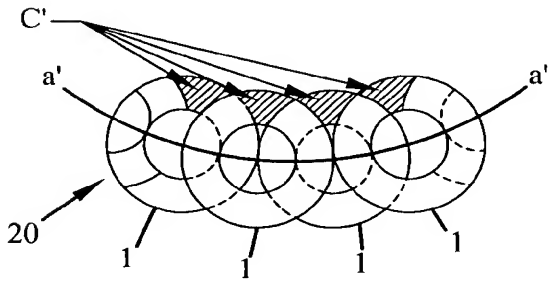


FIG. 9



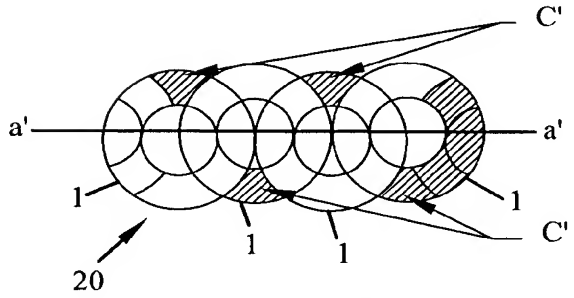


FIG. 10

FIG. 13

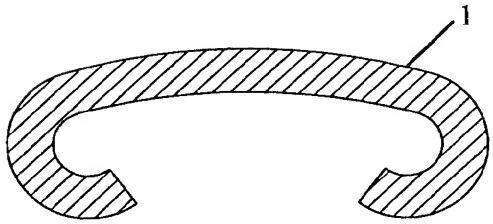


FIG. 14

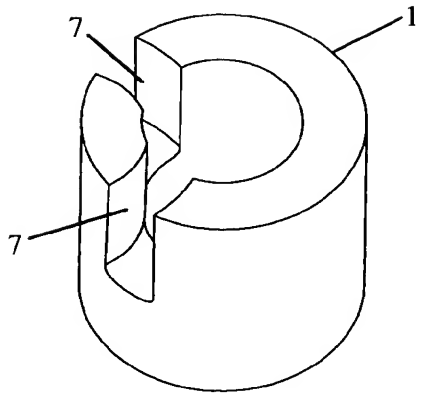


FIG. 15

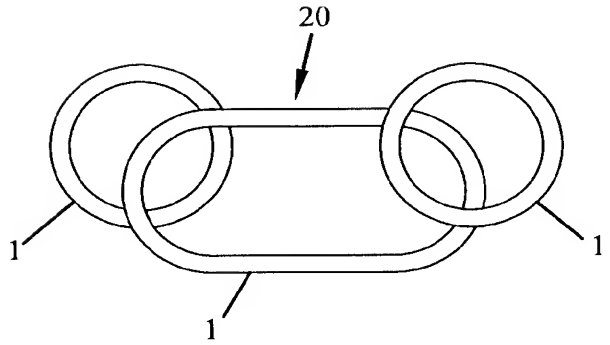
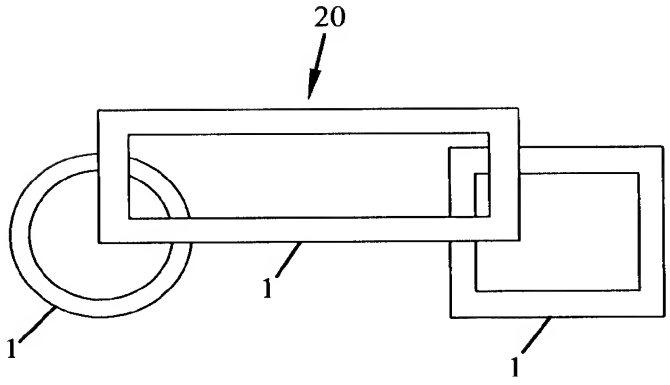


FIG. 16



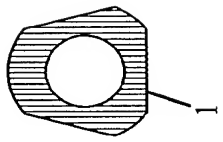


FIG. 17A

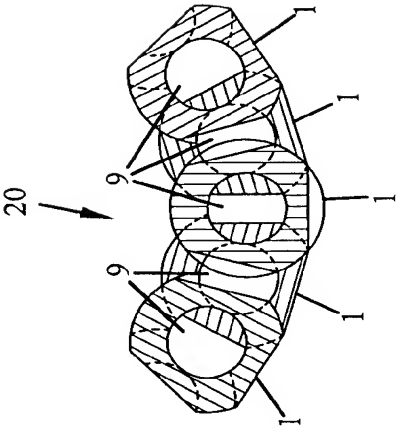


FIG. 17B

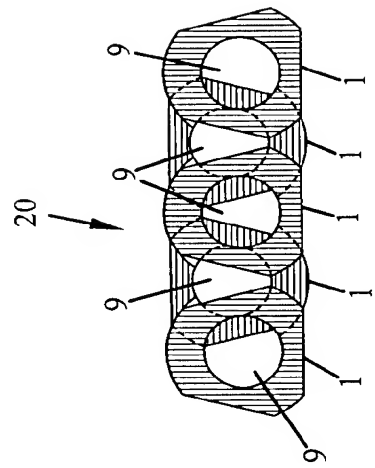
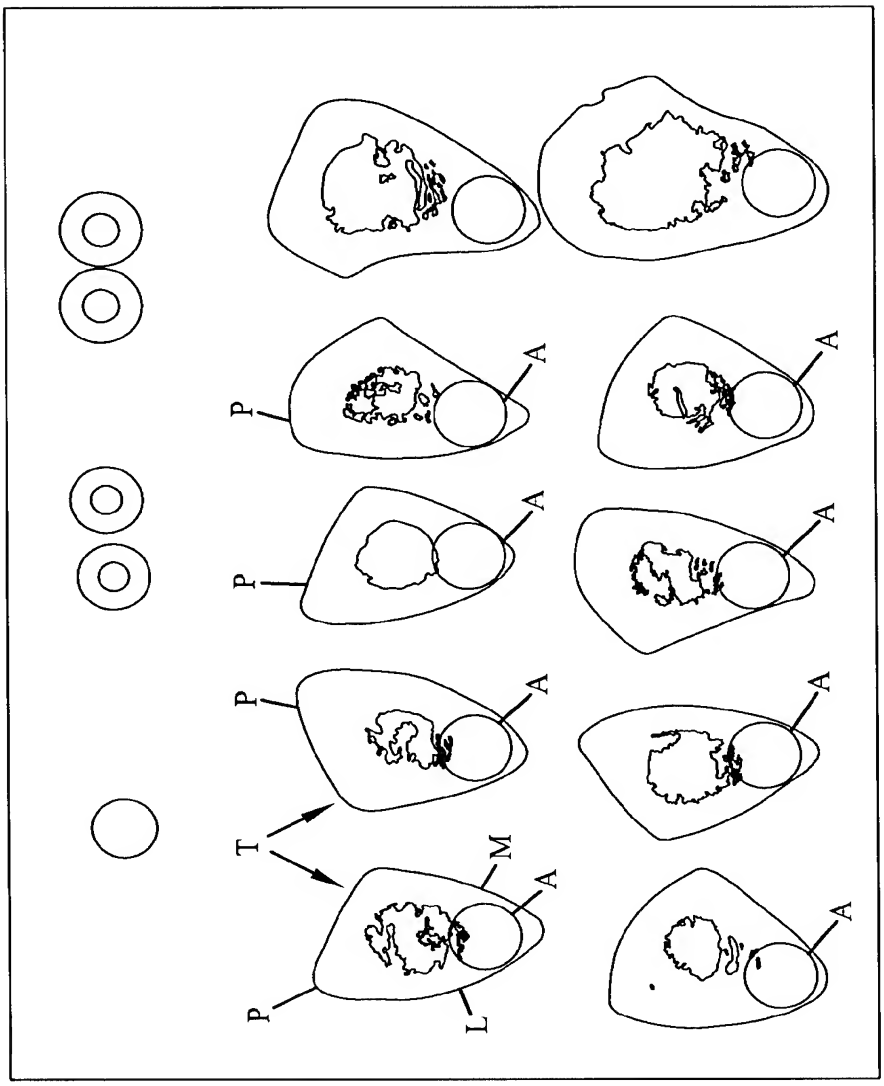


FIG. 17C

FIG. 18



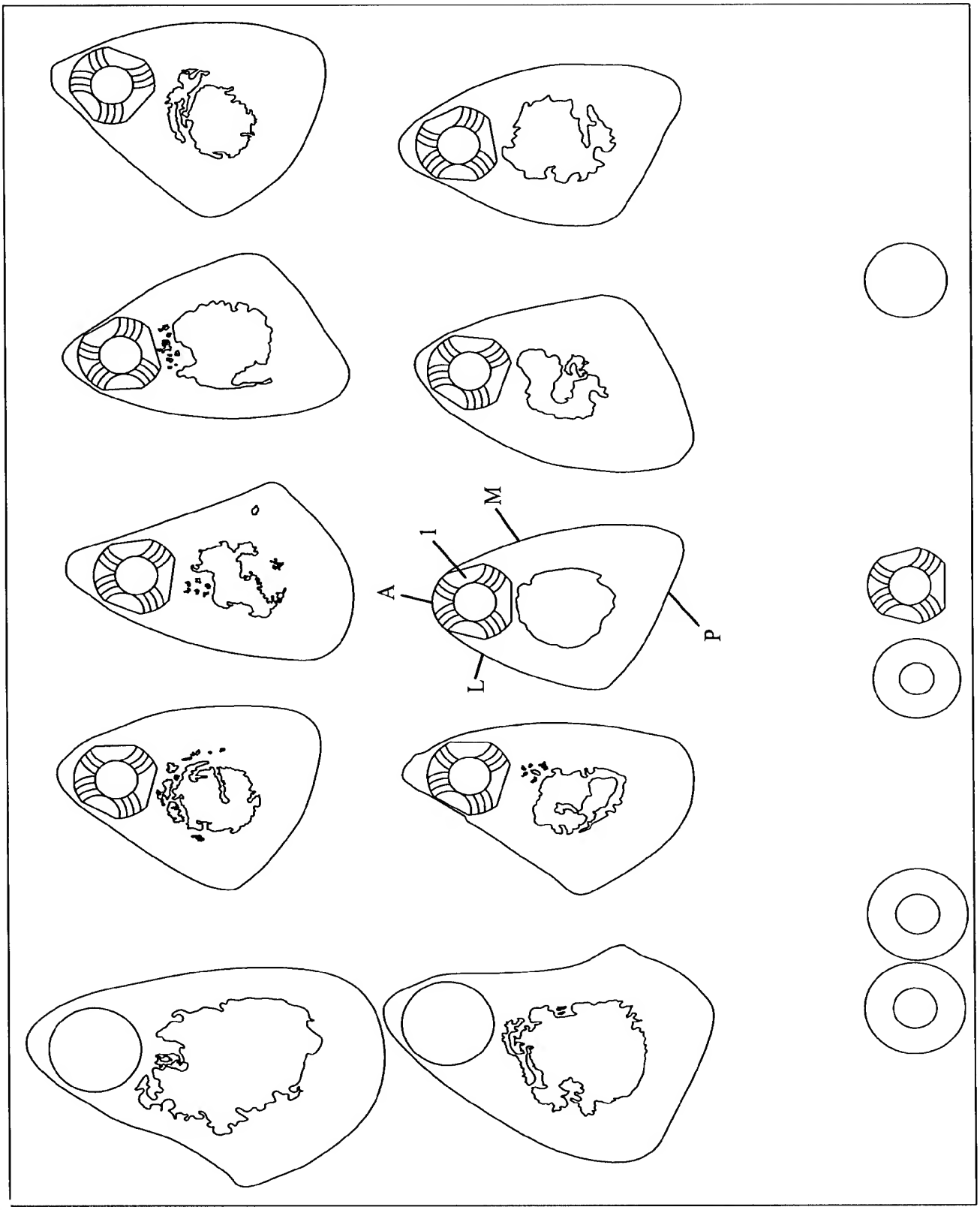


FIG. 19

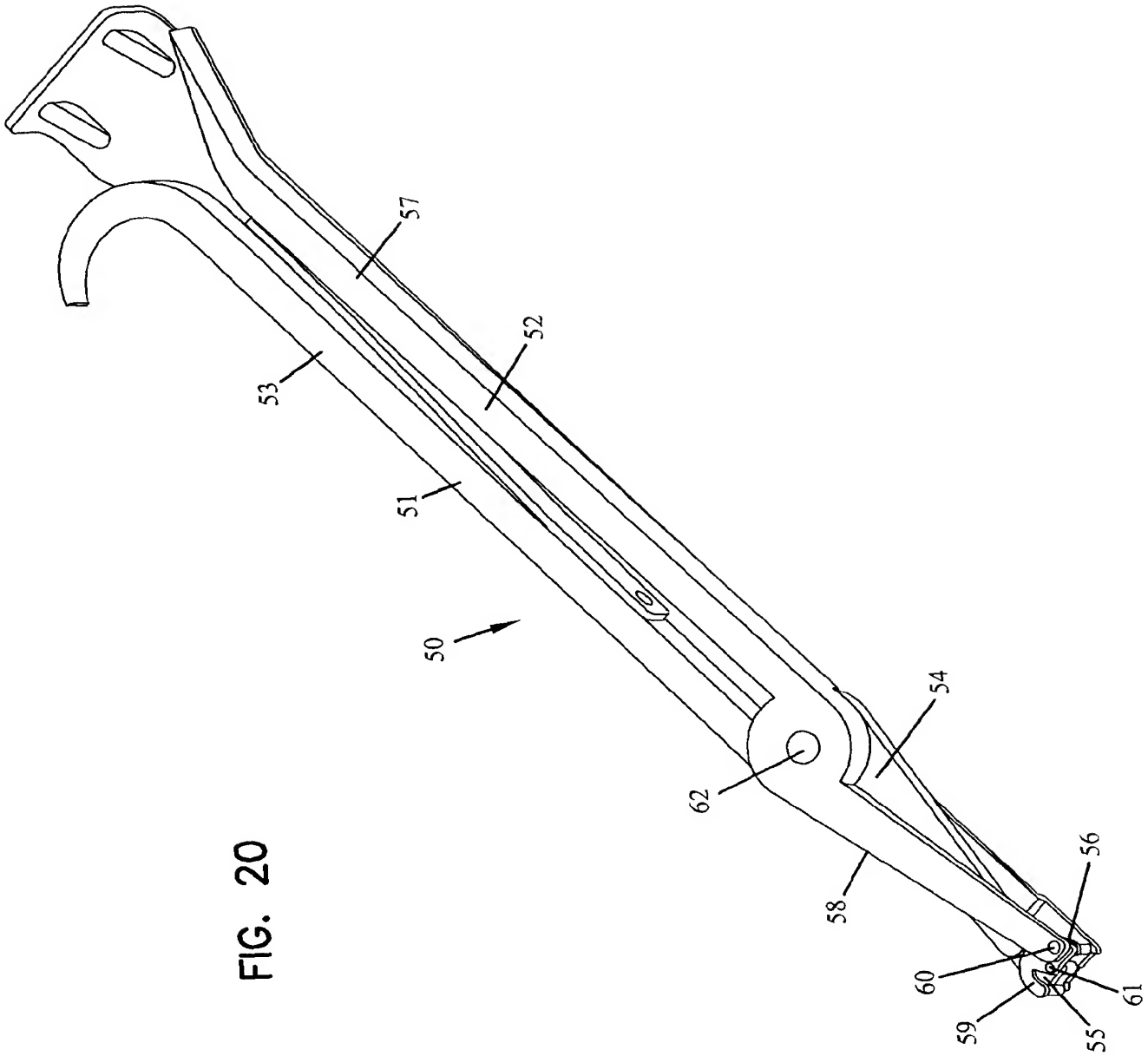


FIG. 20

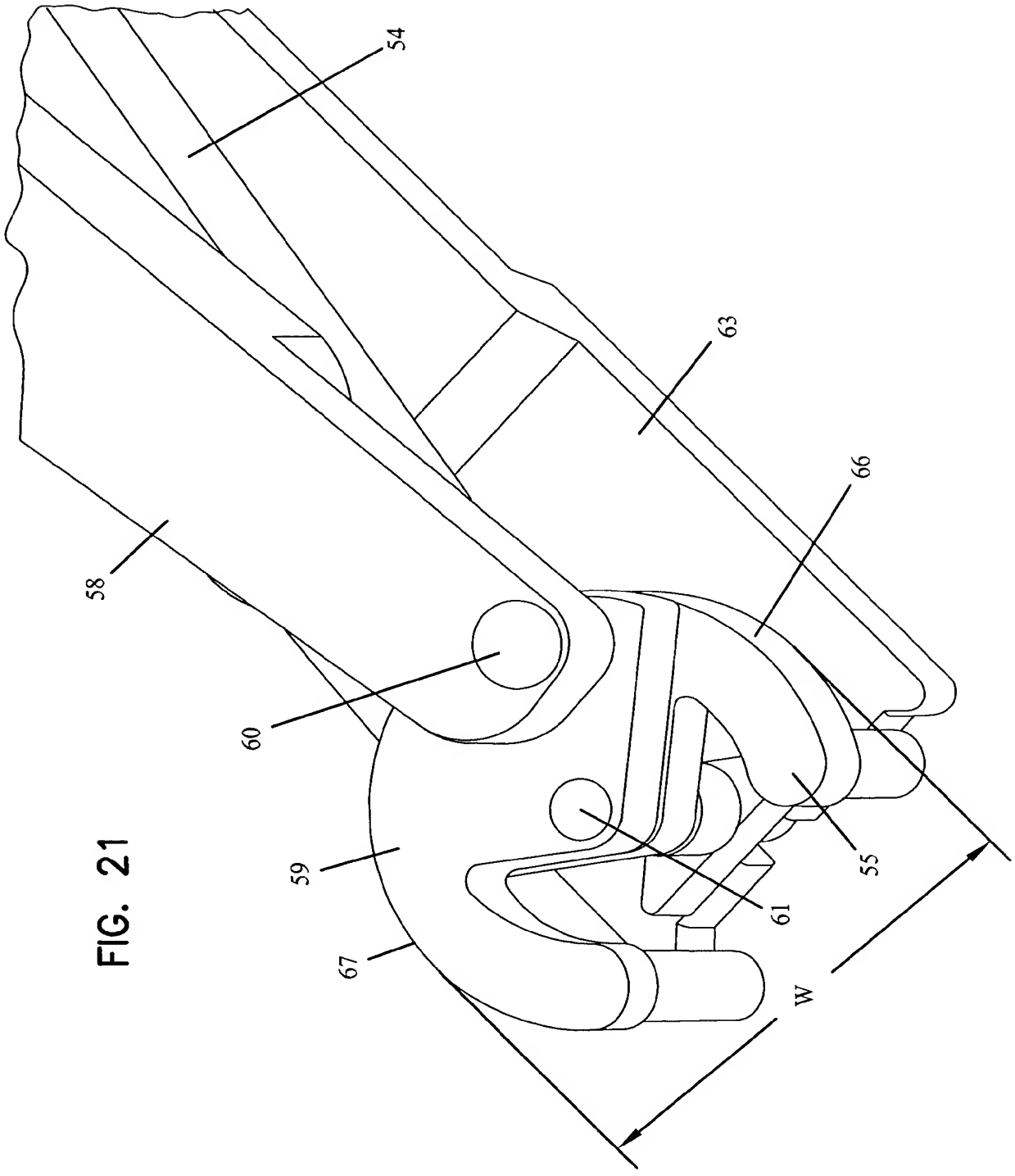


FIG. 21

FIG. 22

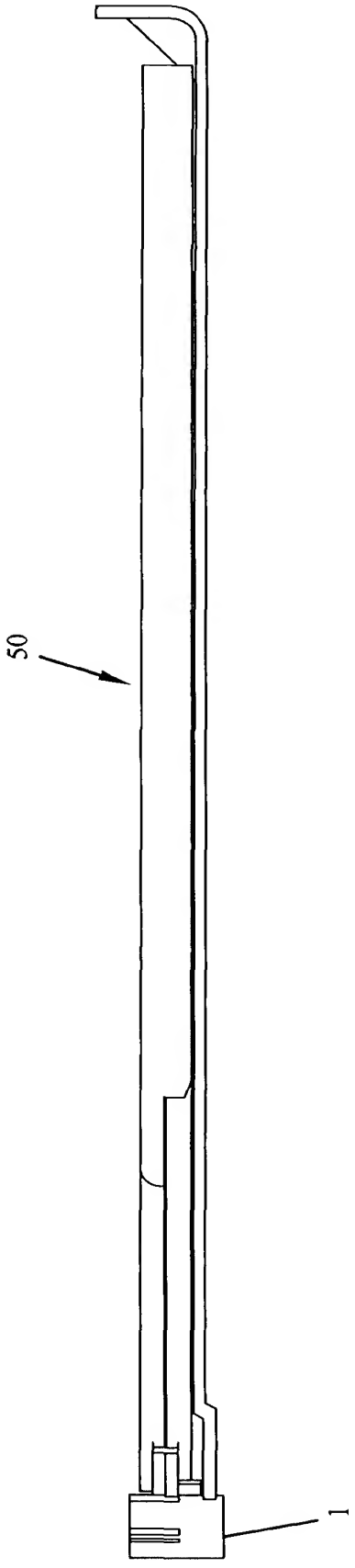
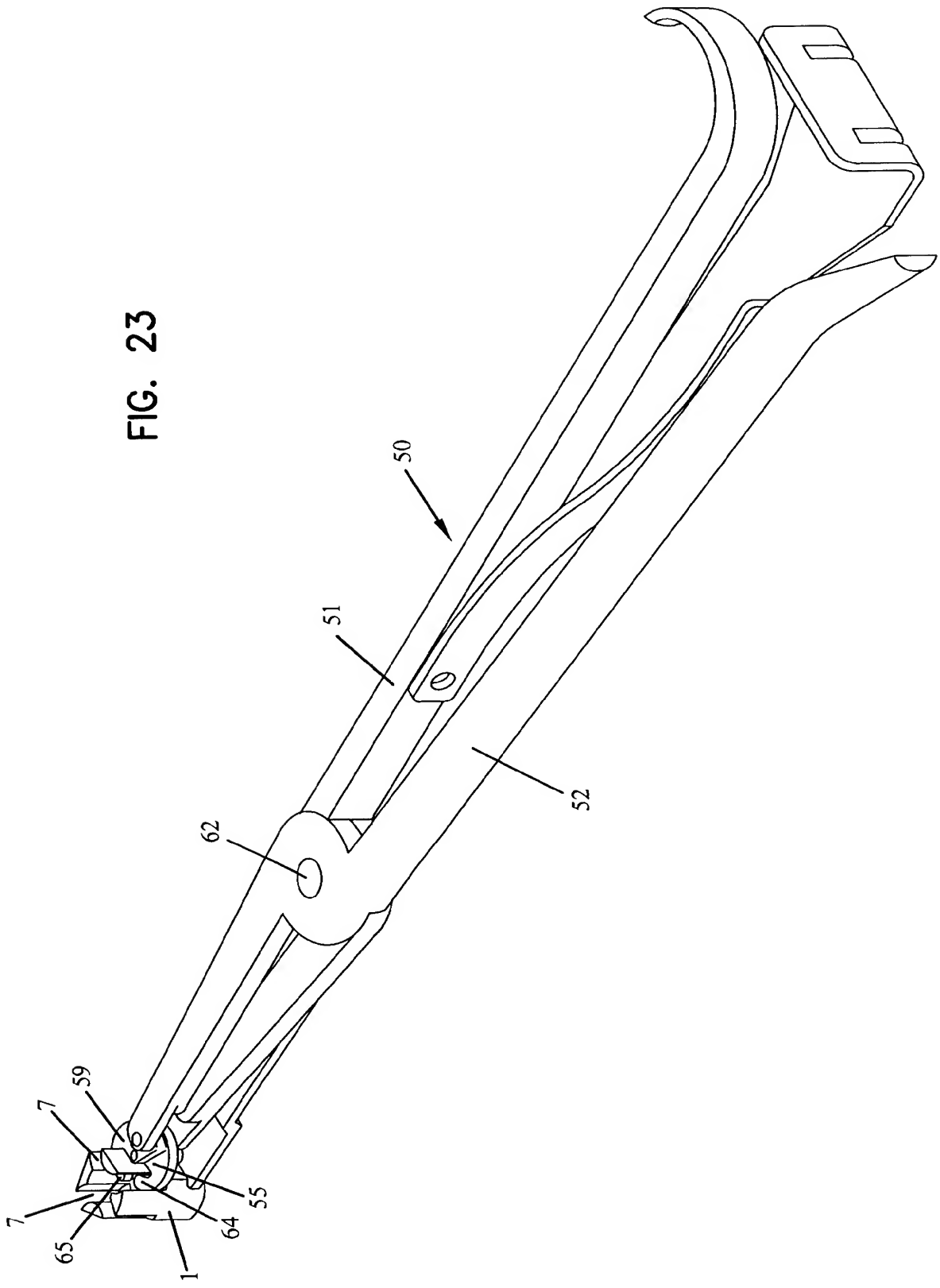


FIG. 23



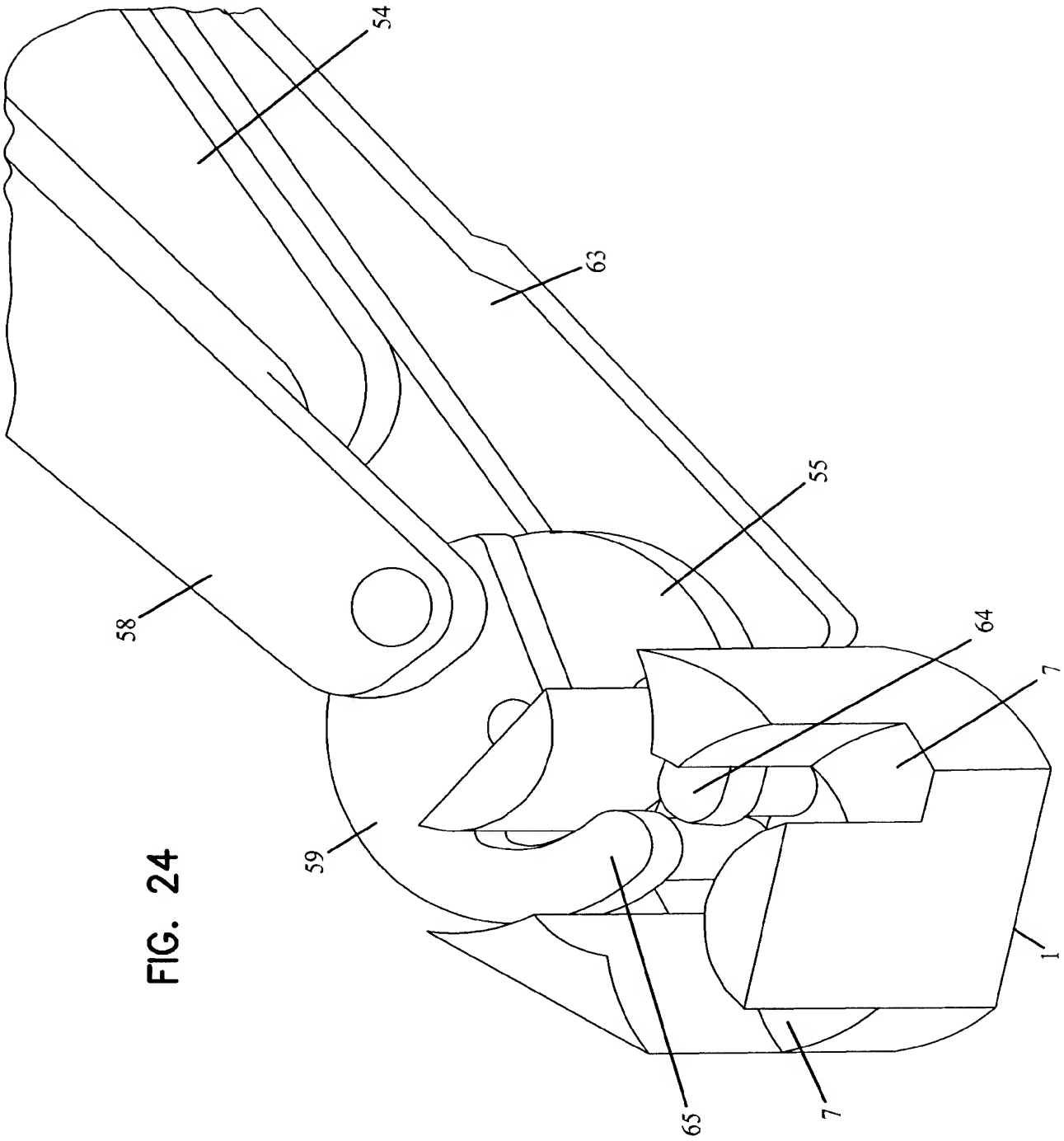


FIG. 24

INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/US 02/31013

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 60837 A (NUVASIVE INC) 2 December 1999 (1999-12-02) page 6, line 23 - line 26 page 16, line 12 - line 16 page 16, line 25 -page 17, line 6 figures 14,15	1,7,9, 10,12,16
A	US 5 893 890 A (PISHARODI MADHAVAN) 13 April 1999 (1999-04-13) column 3, line 8 - line 18 column 3, line 59 -column 4, line 7 column 4, line 30 - line 32 figures 1,2	1
A	US 6 193 757 B1 (EBNER HARALD ET AL) 27 February 2001 (2001-02-27) column 11, line 36 -column 12, line 12 figures 21,22	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 December 2002	08/01/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Storer, J

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

rnational application No.
PCT/US 02/31013

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 18-20
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 02/31013

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		EP 1124512 A1	22-08-2001

INTERNATIONAL SEARCH REPORT

formation on patent family members

Int ›nal Application No
PCT/US 02/31013

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6193757 B1		JP 2002528223 T	03-09-2002
		WO 0025706 A1	11-05-2000
		US 2002151976 A1	17-10-2002
		US 6395031 B1	28-05-2002

(12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION EN MATIÈRE DE BREVETS (PCT)

(19) Organisation Mondiale de la Propriété Intellectuelle
Bureau international

(43) Date de la publication internationale
21 août 2003 (21.08.2003)

PCT

(10) Numéro de publication internationale
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(51) Classification internationale des brevets[7] : A61F 2/44

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PCT/FR03/00438

(22) Date de dépôt international :
11 février 2003 (11.02.2003)

(25) Langue de dépôt : français

(26) Langue de publication : français

(30) Données relatives à la priorité :
02/01654 11 février 2002 (11.02.2002) FR

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(72) Inventeur; et

(75) Inventeur/Déposant *(pour US seulement)* : **PETIT, Dominique** [FR/FR]; 2, rue des Peupliers, F-62180 Verton (FR).

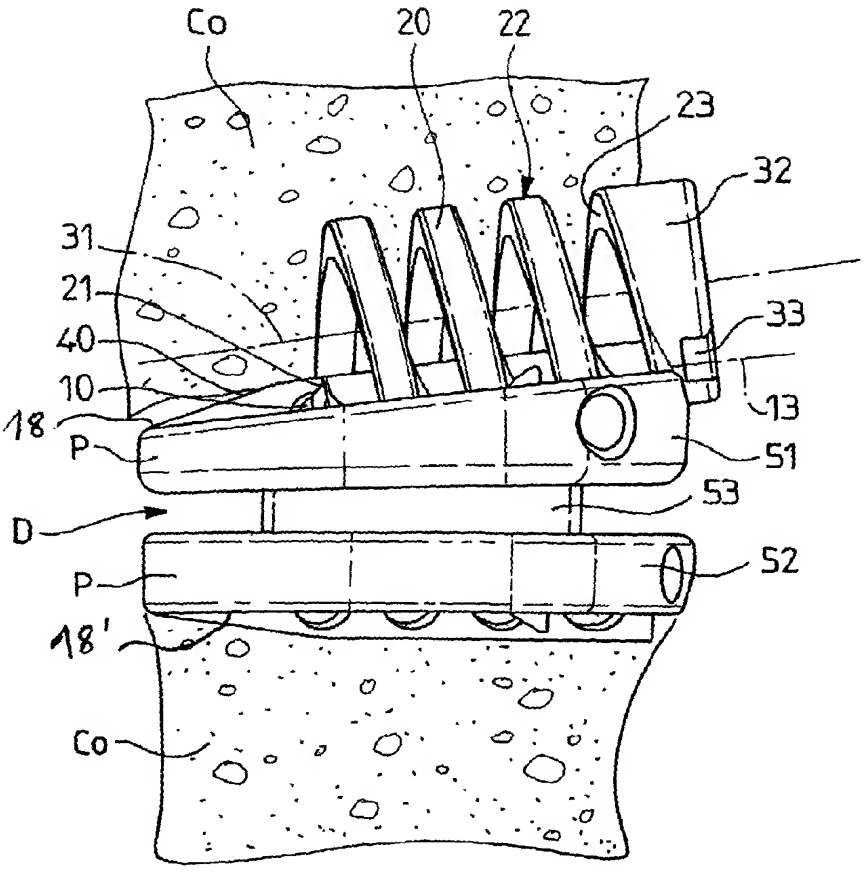
(74) Mandataires : **BREESE, Pierre** etc.; Breese-Majerowicz, 3, avenue de l'Opéra, F-75001 Paris (FR).

(81) États désignés *(national)* : AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM,

[Suite sur la page suivante]

(54) Title: SYSTEM FOR FIXING A PART TO A BONE ELEMENT

(54) Titre : SYSTEME PERMETTANT DE FIXER UNE PIECE SUR UN CORPS OSSEUX



(57) Abstract: The invention relates to a system S which is used to fix a part P to a bone element Co. The invention is essentially characterised in that it consists of: at least one hole (10) which is disposed in part P; a rigid rod (20) comprising a first end (21), said rod being wound into a spiral (22) along a first helicoidal curve; and means (30) of rotating the rod (20) around the axis (31) of the first helicoidal curve, such that the first end (21) of the rod (20) moves alternatively inside and outside the bone element (Co) and, during the rotation thereof, the first end (21) of the rod (20) moves at least once into the opening (10). The invention is particularly suitable for fixing intervertebral discs (51, 52) or fusion cages to the vertebral bodies of two consecutive vertebrae.

(57) Abrégé : La présente invention concerne les systèmes S permettant de fixer une pièce P sur un corps osseux Co. Le système selon l'invention se caractérise essentiellement par le fait qu'il comporte au moins une percée 10 réalisée dans la pièce P, une tige rigide 20 comportant une première extrémité 21, la tige

[Suite sur la page suivante]

WO 03/068112 A1

HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) **États désignés** *(régional)* : brevet ARIPO (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), brevet eurasien (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), brevet européen (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), brevet OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Publiée :

— *avec rapport de recherche internationale*

— *avant l'expiration du délai prévu pour la modification des revendications, sera republiée si des modifications sont reçues*

En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

étant enroulée en spirale 22 selon une première courbe hélicoïdale, et des moyens 30 pour entraîner la rotation de la tige 20 autour de l'axe 31 de la première courbe hélicoïdale de façon que la première extrémité 21 de la tige 20 passe alternativement dans le corps Co et en dehors du corps, et que, dans son mouvement de rotation, la première extrémité 21 de la tige 20 passe au moins une fois dans la percée10. Application, notamment, à la fixation des plateaux 51, 52 de disques intervertébraux, de cages intersomatiques, sur les corps vertébraux de deux vertèbres consécutives.

SYSTEME PERMETTANT DE FIXER UNE PIECE SUR UN CORPS OSSEUX

La présente invention concerne les systèmes permettant de fixer une pièce sur un corps osseux, qui trouvent une application particulièrement avantageuse dans le domaine rachidien pour la fixation, par exemple, d'une cage intersomatique ou d'un disque intervertébral sur les corps vertébraux de deux vertèbres consécutives.

Il est déjà connu des prothèses intervertèbrales qui sont implantées entre les deux corps vertébraux de deux vertèbres. Ces prothèses comportent par exemple des plateaux qui doivent être respectivement fixés aux deux corps vertébraux.

En général, quand on veut fixer une pièce, par exemple métallique, sur un corps osseux et que l'on veut que cette pièce soit immédiatement solidaire de ce corps osseux, on utilise des vis ou analogues. Mais il arrive parfois que l'emplacement de cette pièce par rapport au corps osseux sur lequel elle doit être fixée ne permet pas l'utilisation de vis ou analogues, car il n'y a pas assez d'espace de recul devant la pièce par rapport au corps osseux pour pouvoir pré-positionner les vis avant de les visser dans le corps osseux en les passant préalablement par des lumières ou analogues réalisées dans la pièce.

En palliatif, sont utilisés des moyens comme des picots, nervures, etc. qui sont ancrés dans la partie superficielle du corps osseux. En revanche, la solidarisation entre la pièce et le corps osseux ne peut dans ce cas se faire que par la repousse naturelle de l'os, c'est-à-dire par ostéosynthèse, en intercalant si nécessaire un produit favorisant cette ostéosynthèse, par exemple de l'hydroxy-apatite et/ou un métal biocompatible poreux ou non, ou analogue.

Cette dernière solution n'est pas pratique car il est dans ce cas nécessaire d'interdire au patient sur lequel est implantée une telle pièce de prothèse de ne pas avoir de mouvements importants tant que la solidification par ostéosynthèse n'est pas définitive.

La présente invention a donc pour but de réaliser un système permettant de pallier les inconvénients rapportés ci-dessus des systèmes de l'art antérieur pour la fixation d'une pièce, par exemple métallique, sur un corps osseux, et qui trouvent une application particulièrement avantageuse dans les prothèses rachidiennes.

Plus précisément, la présente invention a pour objet un système permettant de fixer une pièce sur un corps osseux selon la revendication 1.

Ce système comporte :

- une tige comportant une première extrémité, ladite tige étant enroulée en spirale sensiblement selon une première courbe hélicoïdale par rapport à un axe longitudinal, et

- au moins une percée traversante réalisée dans ladite pièce et présentant une ligne axiale,

- des moyens pour entraîner la rotation de ladite tige autour de l'axe de ladite première courbe hélicoïdale de façon que la première extrémité de ladite tige passe alternativement dans le corps et en dehors du corps, et que, dans son mouvement de rotation, ladite première extrémité de la tige passe au moins une fois dans ladite percée traversante.

La pièce à fixer sur le corps osseux comporte, de préférence, une pluralité de percées traversantes, les lignes axiales de ces percées traversantes étant sensiblement perpendiculaires à l'axe longitudinal de la première courbe hélicoïdale, la section transversale des percées de cette dite pluralité de percées traversantes étant au moins égale à la section transversale maximale de ladite tige.

La ou les lignes axiales respectivement de la ou des percées traversantes est ou sont, soit droite(s) et sensiblement perpendiculaire(s) à l'axe longitudinal de la première courbe hélicoïdale, soit définie(s) sensiblement selon une seconde courbe hélicoïdale.

Ladite pièce à fixer comporte, de préférence, une nervure en saillie, la hauteur de ladite nervure, prise à partir des bords des dites percées traversantes, étant inférieure au diamètre intérieur de la spirale et cette nervure étant réalisée, de manière préférée, selon une ligne axiale sensiblement parallèle à l'axe longitudinal de la première courbe hélicoïdale.

La section transversale de ladite tige peut avoir sensiblement la forme d'un quadrilatère rectangle, d'un cercle, ou tout autre forme.

Lesdites première et seconde courbes hélicoïdales sont, de préférence, sensiblement identiques et la ou les première et/ou seconde courbe(s) hélicoïdale(s) est ou sont, de préférence également, de pas constant.

La ou les percée(s) traversante(s) comporte(nt), de préférence, chacune au moins une rampe bordant respectivement au moins une extrémité de chaque percée traversante pour guider le passage de la première extrémité de ladite tige dans lesdites percées.

Dans une variante, les moyens pour entraîner la rotation de la tige autour de l'axe de la première courbe hélicoïdale comportent une tête solidaire de la seconde extrémité de ladite tige, ladite tête comportant des moyens aptes à coopérer avec un ancillaire d'entraînement en rotation.

Dans cette variante, la tête présente, de préférence, une forme annulaire dont les diamètres intérieur et extérieur sont respectivement sensiblement égaux aux diamètres intérieur et extérieur de ladite spirale.

Le nombre de percées traversantes est, de préférence, sensiblement égal au nombre de spires de ladite spirale.

L'extrémité de la tige est, de préférence, pointue ou en biseau.

Dans une variante, ladite spirale présente une forme auto-taraudeuse.

La présente invention se rapporte également à une tige pour un système selon l'invention, à une cage intersomatique comportant au moins un système selon l'invention et à un disque intervertébral artificiel comportant deux plateaux dont un au moins et de préférence les deux comporte(nt) un système selon l'invention.

Avantageusement, le système selon l'invention est simple et facile à fabriquer et à implanter. Il ne nécessite pas d'endommager d'une manière importante le corps osseux.

De plus, le système selon l'invention est relativement simple à retirer lorsque cette opération est nécessaire.

D'autres caractéristiques et avantages de la présente invention apparaîtront au cours de la description suivante donnée en regard des dessins annexés à titre illustratif mais nullement limitatif, dans lesquels :

- Les figures 1 et 2 représentent deux vues en coupe d'un mode de réalisation du système selon l'invention permettant de fixer une pièce sur un corps osseux, la figure 1 étant une coupe référencée I-I sur la figure 2, la figure 2 étant une coupe référencée II-II sur la figure 1, et

- Les figures 3 et 4 représentent respectivement une vue en coupe et une vue en perspective cavalière, d'un autre mode de réalisation du système selon l'invention dans une application à la fixation des deux plateaux d'un disque intervertébral respectivement sur les deux corps vertébraux de deux vertèbres consécutives.

Il est précisé que, bien que les figures représentent plusieurs modes de réalisation de l'objet selon l'invention, les mêmes références y désignent les mêmes éléments, quelle que soit la figure sur laquelle elles apparaissent et quelle que soit la forme de représentation de ces éléments. De même, si des éléments ne sont pas spécifiquement référencés sur l'une des figures, leurs références peuvent être aisément retrouvées en se reportant à une autre figure.

La présente invention concerne un système S permettant de fixer une pièce P sur un corps osseux Co.

La pièce P comporte au moins une percée traversante 10 réalisée, par exemple, sur une surface extérieure 18, 18', cette percée traversante ayant une ligne axiale 10_x.

Le système S une tige rigide 20 comportant une première extrémité 21 conformée pour être apte à pénétrer dans le corps Co, la tige étant enroulée en spirale 22 sensiblement selon une première courbe hélicoïdale.

Le système comporte en outre des moyens 30 pour entraîner la rotation de la tige 20 autour de l'axe 31 de la première courbe hélicoïdale de façon que la première extrémité 21 de la tige 20 passe alternativement dans le corps Co et en dehors du corps, et que, dans son mouvement de rotation en dehors du corps Co, la première extrémité 21 de la tige 20, par exemple pointue ou en biseau, passe au moins une fois dans la percée traversante 10.

Il est précisé que la section transversale de la percée traversante 10 peut être circulaire et d'une section légèrement supérieure à la section maximale de la tige 20. Dans ce cas, la tige 20 ne passe qu'une seule fois dans cette percée. Mais il peut aussi être réalisé une percée de section transversale oblongue et de largeur au moins égale à la section maximale de la tige 20 et de longueur au moins égale à un multiple du pas de la spirale hélicoïdale 22. Dans ce cas, la première extrémité 21 de la tige passe, ou peut passer, plusieurs fois dans la même percée traversante.

Cette dernière réalisation est possible mais, de façon avantageuse, le système comporte une pluralité de percées traversantes 10, 11, 12, ..., comme illustré sur toutes les figures, réalisées dans la pièce P, présentant chacune respectivement une ligne axiale 10_x, 11_x, 12_x, ...

Dans une variante, les lignes axiales 10_x, 11_x, 12_x, ... de ces percées traversantes sont sensiblement définies selon une seconde courbe hélicoïdale, la section transversale des percées de cette pluralité étant au moins égale à la section transversale maximale de la tige 20 de façon que la tige puisse y coulisser relativement aisément.

Dans une autre variante, les percées traversantes 10, 11, 12, ... sont réalisées dans la pièce P de façon que leurs lignes axiales 10_x, 11_x, 12_x, ... soient toutes sensiblement perpendiculaires à une même droite 13, elle-même parallèle à l'axe 31, pour favoriser la pénétration de la tige 20 dans l'os et l'aider à passer plus facilement dans ces percées.

Pour favoriser la mise en place de la pièce P sur le corps Co et lui donner, dès sa mise en place, une première position relativement stable, il est avantageux que le système comporte en outre, comme illustré sur les figures, une nervure en saillie 40 réalisée sur la pièce P éventuellement apte à coopérer, par exemple par enfichage, avec une rainure complémentaire préalablement réalisée dans le corps osseux Co. La hauteur de la nervure, prise à partir des bords des percées traversantes, est, bien entendu, inférieure au diamètre intérieur de la spirale 22.

En outre, de façon très préférentielle, la nervure 40 est réalisée selon une ligne axiale sensiblement parallèle à l'axe 31 et est sensiblement contenue dans un plan défini par la droite 13 et l'axe 31 de la seconde courbe hélicoïdale en spirale 22.

Cette nervure 40 permet d'augmenter le maintien au niveau de la coopération entre les parois des percées traversantes et la spirale 22.

Dans une réalisation préférentielle qui facilite la réalisation de la spirale 22, la section transversale de la tige 20 a sensiblement la forme d'un quadrilatère rectangle, par exemple un carré ou un rectangle, éventuellement d'un trapèze dont la grande base est peu différente de la petite et dont la forme peut alors s'apparenter à celle d'un rectangle.

Il est aussi précisé que les première et seconde courbes hélicoïdales définies ci avant, sont avantageusement sensiblement identiques et ont de préférence un pas constant.

Dans le but de favoriser le guidage de la première extrémité 21 de la tige 20 lors de sa pénétration dans chaque percée traversante, la ou les percée(s) traversante(s) 10, 11, 12, ... comporte(nt) chacune au moins une rampe 14, 15

bordant respectivement au moins une extrémité 16, 17 de chaque percée traversante pour guider le passage de la première extrémité 21 de ladite tige 20 dans lesdites percées. Dans cette configuration, les lignes axiales 10_x, 11_x, 12_x, ..., tout en restant perpendiculaires à la droite 13, sont arrondies transversalement selon un rayon de courbure supérieure au rayon extérieur de la spirale 22, comme on peut le voire sur la figure 1.

Le système comporte de façon avantageuse des rampes 14, 15 bordant respectivement chacune des deux extrémités 16, 17 de chaque percée traversante.

Ces rampes, visibles sur les figures 2 et 4, adoptent la forme de portions de surface hélicoïdale en creux très voisine de celle de la surface extérieure de la spirale 22 définie auparavant.

Comme mentionné ci avant, le système comporte des moyens 30 pour entraîner la rotation de la tige 20 autour de l'axe 31 de la seconde courbe hélicoïdale. Ces moyens peuvent par exemple être constitués par la seconde extrémité 23 de la tige 20 en spirale 22. Cependant, il est préférable qu'ils comportent une tête 32 solidaire de cette seconde extrémité 23 de la tige 20, cette tête comportant des moyens 33 aptes à coopérer avec un ancillaire d'entraînement en rotation, par exemple équivalent à un tournevis, une clé à tube ou analogue.

Il est aussi très avantageux que la tête 32 présente une forme annulaire dont les diamètres intérieur et extérieur sont respectivement sensiblement égaux aux diamètres intérieur et extérieur de la spirale 22, ce qui permet d'obtenir une réalisation simultanée de la spirale 22 et de la tête 32, par usinage d'un tube cylindrique de révolution en titane ou analogue.

Cette réalisation de la tête de forme annulaire présente en outre un avantage lors de la mise en place de la spirale. En effet, la tête sert alors de butée pour définir la position limite de la spirale 22 par rapport à pièce P, comme illustré sur les figures 3 et 4.

Dans une réalisation possible préférentielle, le nombre de percées 10, 11, 12, ... est sensiblement égal au nombre de spires de la spirale 22, ce qui permet d'obtenir une relativement bonne fixation de la pièce P sur le corps osseux Co, avec une longueur minimale de spirale.

Le système selon l'invention peut être utilisé dans de nombreux domaines, mais trouve des applications particulièrement avantageuses pour les procédés de fixation de cages intersomatiques ou de disques intervertébraux.

Pour faciliter l'implantation du système selon l'invention, il peut être requis de réaliser au préalable un taraudage du corps osseux, afin de réaliser dans la paroi une forme sensiblement hélicoïdale qui est exactement complémentaire de la forme de la spirale 22. Cette opération est alors réalisée à l'aide d'un instrument de taraudage.

Une fois le taraudage réalisé, la spirale de la prothèse est vissée dans le taraudage.

Il est également possible d'utiliser une spirale auto-taraudante. Cela permet d'éviter l'étape de taraudage préalable du corps osseux. La spirale (22) de la prothèse est alors directement vissée dans le corps osseux.

Les figures 3 et 4 représentent, à titre illustratif, le système selon l'invention utilisé pour fixer les deux plateaux 51, 52, d'un disque intervertébral artificiel D coopérant entre eux par des moyens de rotule 53 ou analogue, avec respectivement les deux corps vertébraux de deux vertèbres consécutives.

Le système de fixation tel que décrit ci-dessus fonctionne et s'utilise dans ce cas de la façon suivante:

Quand il est nécessaire d'implanter, par exemple, un disque intervertébral artificiel D entre deux corps vertébraux, on l'introduit en le glissant entre les deux corps vertébraux, si nécessaire préalablement soumis à une légère distraction. Deux tiges hélicoïdales en spirale 22 sont alors respectivement introduites comme décrit auparavant en passant alternativement dans l'os des corps vertébraux et respectivement dans les percées traversantes de chaque plateau du disque intervertébral, la première extrémité 21 de chaque tige passant, à chaque tour complet de la spirale lorsque la tige est entraînée en rotation par la tête 32, dans une percée 10, 11, 12, ...

Sur les figures 1 et 4, la flèche 19 illustre le sens du mouvement de vissage de la spirale 22 dans la structure vertébrale pour l'implantation du système S.

Le système selon l'invention s'utilisera de la même façon que décrit ci-dessus , pour fixer au moins l'une des deux surfaces extérieure opposées d'une cage intersomatique sur au moins l'un des deux corps vertébraux de deux vertèbres

consécutives, les percées traversantes étant réalisées sur les faces opposées de la cage.

Le système de fixation décrit ci-dessus présente deux avantages primordiaux par rapport aux systèmes de l'art antérieur qui ne comportaient que des picots et/ou nervures, avec éventuellement des produits favorisant l'ostéosynthèse entre les faces en regard venant en contact, respectivement des plateaux et des corps vertébraux.

Le premier de ces deux avantages est le fait qu'il est alors possible d'introduire le disque intervertébral ou la cage sans avoir à réaliser une distraction importante entre les deux corps vertébraux, alors que, avec les systèmes de l'art antérieur, il était nécessaire de distracter les deux corps vertébraux d'au moins une valeur double de la hauteur des picots et/ou nervures.

Le second de ces deux avantages est le fait que la fixation permet d'obtenir ce que les techniciens appellent une stabilité primaire qui permet au patient d'effectuer des mouvements qui ne lui étaient pas autorisés avec les systèmes de l'art antérieur qui l'obligeaient à attendre une consolidation osseuse importante, généralement de l'ordre de quelques semaines.

Pour l'ablation du système S, la spirale est simplement dévissée en tournant la cage dans le sens inverse de la flèche 19. Il n'est pas nécessaire de casser le corps osseux pour libérer la spirale 22.

L'invention est décrite dans ce qui précède à titre d'exemple. Il est entendu que l'homme du métier est à même de réaliser différentes variantes de l'invention sans pour autant sortir du cadre du brevet.

REVENDICATIONS

1. Système (S) permettant de fixer une pièce (P) sur un corps osseux (Co), caractérisé en ce qu'il comporte:

- une tige (20) comportant une première extrémité (21), ladite tige (20) étant enroulée en spirale (22) sensiblement selon une première courbe hélicoïdale par rapport à un axe longitudinal (31), et
- au moins une percée traversante (10) réalisée dans ladite pièce (P) et présentant une ligne axiale (10_x),
- des moyens (30) pour entraîner en rotation ladite tige (20) autour de l'axe (31) de façon que la première extrémité (21) de ladite tige (20) passe alternativement dans le corps (Co) et en dehors du corps, et que, dans son mouvement de rotation, ladite première extrémité (21) de la tige (20) passe au moins une fois dans ladite percée traversante (10).

2. Système selon la revendication 1, caractérisé en ce que ladite pièce (P) comporte une pluralité de percées traversantes (10, 11, 12, ...), les lignes axiales (10_x, 11_x, 12_x, ...) de ces percées traversantes étant sensiblement perpendiculaires à l'axe longitudinal (31), la section transversale des percées de cette dite pluralité de percées traversantes (10, 11, 12, ...) étant au moins égale à la section transversale maximale de ladite tige (20).

3. Système selon la revendication 1 ou la revendication 2, caractérisé en ce que la ou les lignes axiales (10_x, 11_x, 12_x, ...) respectivement de la ou des percées traversantes (10, 11, 12, ...) est ou sont droite(s) et sensiblement perpendiculaire(s) à l'axe (31).

4. Système selon l'une quelconque des revendications 1 à 3, caractérisé en ce que la ou les lignes axiales (10_x, 11_x, 12_x, ...) respectivement de la ou des percées traversantes (10, 11, 12, ...) est ou sont définie(s) sensiblement selon une seconde courbe hélicoïdale.

5. Système selon l'une quelconque des revendications 1 à 4, caractérisé en ce que ladite pièce (P) comporte une nervure en saillie (40), la hauteur de ladite nervure, prise à partir des bords des dites percées traversantes, étant inférieure au diamètre intérieur de la spirale (22).

6. Système selon la revendication 5, caractérisé en ce que ladite nervure (40) est réalisée selon une ligne axiale sensiblement parallèle à l'axe (31).

7. Système selon l'une quelconque des revendications1 à 6, caractérisé en ce que la section transversale de ladite tige (20) a sensiblement la forme d'un quadrilatère rectangle.

8. Système selon l'une quelconque des revendications1 à 6, caractérisé en ce que la section transversale de ladite tige (20) a sensiblement la forme d'un cercle.

9. Système selon l'une quelconque des revendications4 à 8, caractérisé en ce que lesdites première et seconde courbes hélicoïdales sont sensiblement identiques.

10. Système selon l'une quelconque des revendications 1 à 9, caractérisé en ce que la ou les première et/ou seconde courbe(s) hélicoïdale(s) est ou sont de pas constant.

11. Système selon l'une quelconque des revendications 1 à 10, caractérisé en ce que la ou les percée(s) traversante(s) (10, 11, 12, ...) comporte(nt) chacune au moins une rampe (14, 15) bordant respectivement au moins une extrémité (16, 17) de chaque percée traversante pour guider le passage de la première extrémité (21) de ladite tige (20) dans lesdites percées.

12. Système selon l'une quelconque des revendications 1 à 11, caractérisé en ce que les moyens (30) pour entraîner la rotation de la tige (20) autour de l'axe (31) de la première courbe hélicoïdale comportent une tête (32) solidaire de la seconde extrémité (23) de ladite tige (20), ladite tête comportant des moyens (33) aptes à coopérer avec un ancillaire d'entraînement en rotation.

13. Système selon la revendication 12, caractérisé en ce que la tête (32) présente une forme annulaire dont les diamètres intérieur et extérieur sont respectivement sensiblement égaux aux diamètres intérieur et extérieur de ladite spirale (22).

14. Système selon l'une quelconque des revendications 1 à 13, caractérisé en ce que l'extrémité (21) de la tige (20) est pointue ou en biseau.

15. Système selon l'une quelconque des revendications 1 à 14, caractérisé en ce que le nombre de percées traversantes (10, 11, 12, ...) est sensiblement égal au nombre de spires de ladite spirale (22).

16. Système selon l'une quelconque des revendications 1 à 15, caractérisé en ce que ladite spirale (22) présente une forme auto-taraudeuse.

17. Tige (20) pour un système (S) selon l'une quelconque des revendications 1 à 16, caractérisée en ce que ladite tige (20) comporte une première extrémité (21), ladite tige (20) étant enroulée en spirale (22) sensiblement selon une première courbe hélicoïdale par rapport à un axe longitudinal (31).

18. Cage intersomatique comportant au moins un système (S) selon l'une quelconque des revendications 1 à 16, caractérisée en ce que ladite cage comporte au moins une percée traversante (10) et de préférence plusieurs percées traversantes (10, 11, 12, ...).

19. Disque intervertébral artificiel (D) comportant deux plateaux (51, 52) et au moins un système (S) selon l'une quelconque des revendications 1 à 16, caractérisé en ce qu'au moins un plateau (51, 52), et de préférence les deux x (51, 52), comporte(nt) chacun au moins une percée traversante (10) et de préférence plusieurs percées traversantes (10, 11, 12, ...).

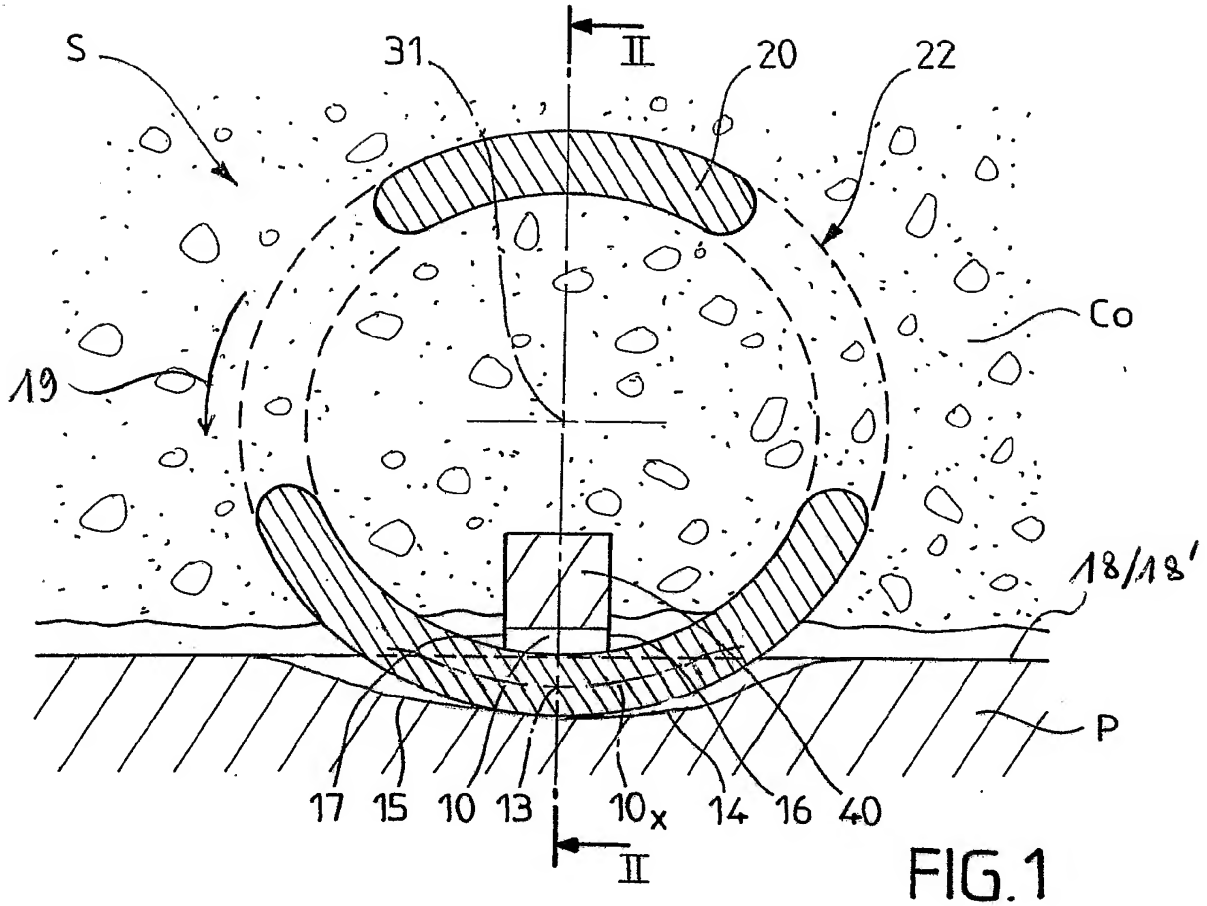

S
31
II
20
22
Co
19
18/18'
P
17
15
10
13
10x
14
16
40
II

FIG.1

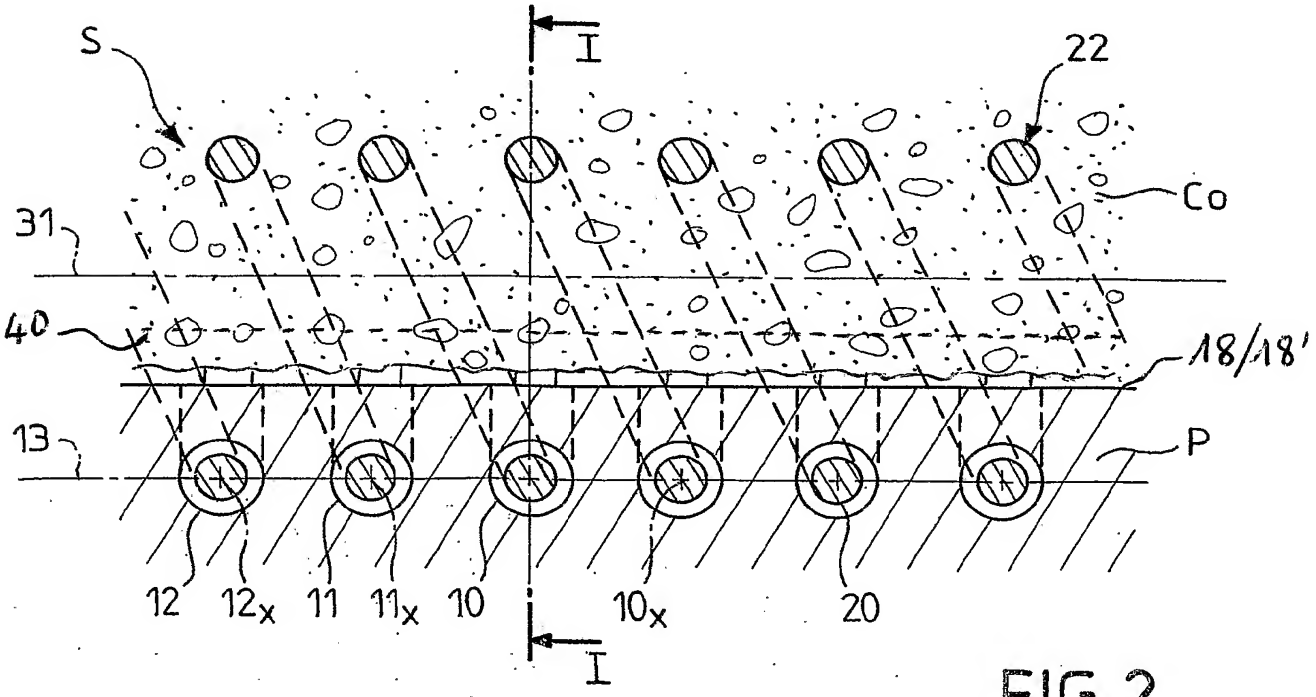

S
I
22
Co
31
40
18/18'
13
P
12
12x
11
11x
10
10x
20
I

FIG.2

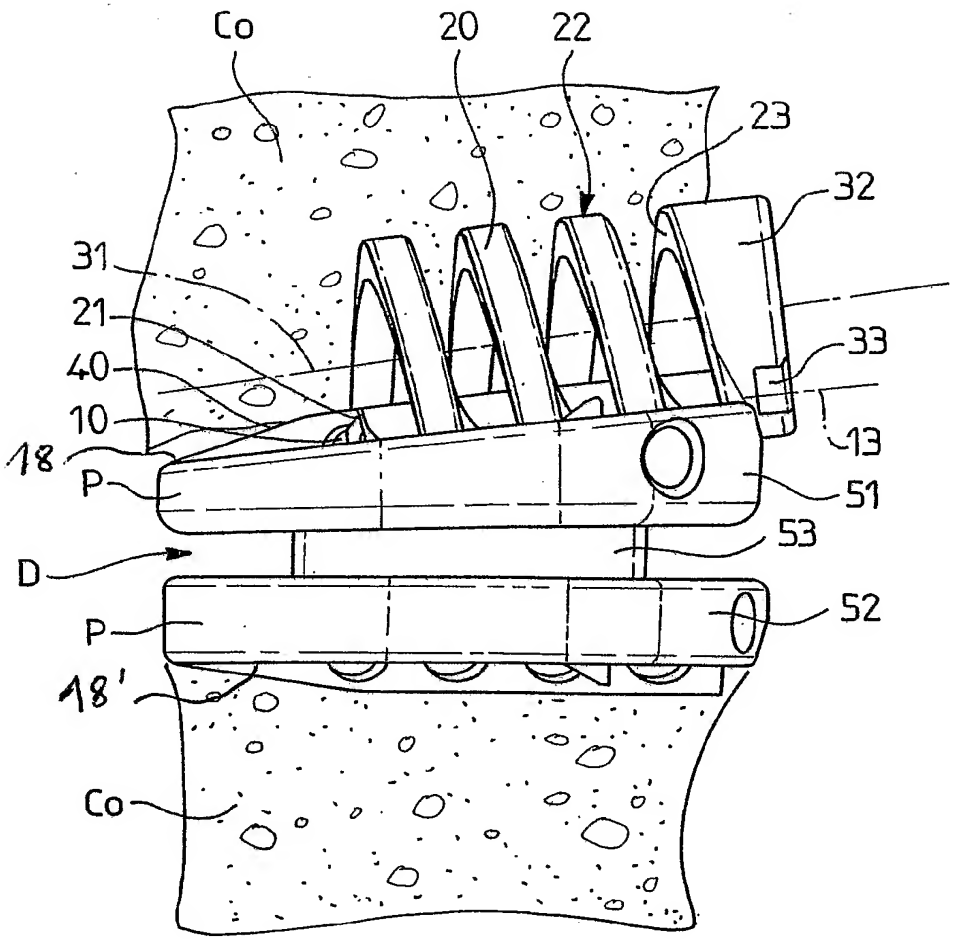

Co
20
22
23
32
31
21
40
33
10
13
18
P
51
53
D
52
P
18'
Co

FIG. 3

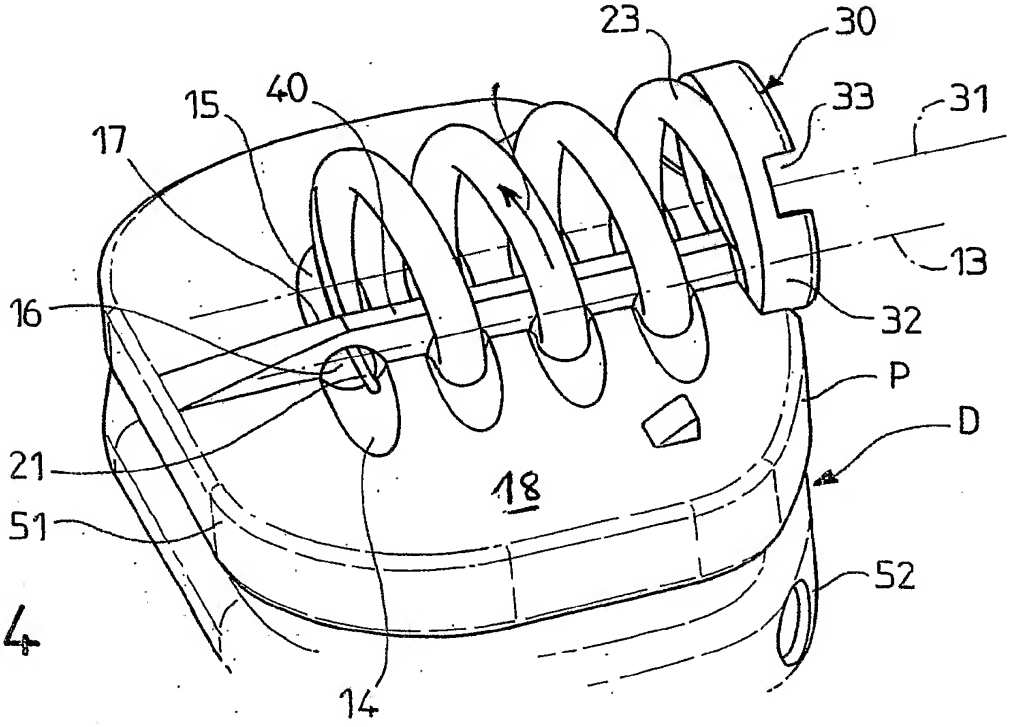

23
30
15
40
33
31
17
13
16
32
P
D
21
18
51
52
14

FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/FR 03/00438

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 02117 A (AESCULAP AG & CO KG ;EISEN GUNTMAR (DE); SCHULTZ ROBERT (DE); WING) 22 January 1998 (1998-01-22) claims 1,3,4; figures ---	1-4, 7-16,18, 19
A	WO 98 48738 A (CROZET YVES ;DIMSO SA (FR)) 5 November 1998 (1998-11-05) claims 1,12; figures 38-40 ---	1-4, 7-16,18, 19
A	US 5 263 953 A (BAGBY GEORGE W) 23 November 1993 (1993-11-23) figures ---	1
A	US 5 423 817 A (LIN CHIH-I) 13 June 1995 (1995-06-13) figures --- -/--	1

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 July 2003	30/07/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Stach, R

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	FR 2 812 188 A (SPINEVISION S A) 1 February 2002 (2002-02-01) claims 1-5; figures 1-4	1
A	US 4 038 703 A (BOKROS JACK C) 2 August 1977 (1977-08-02) claims 1,5,13; figures 1-7	1

INTERNATIONAL SEARCH REPORT

International Application No
PCT/FR 03/00438

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RAPPORT DE RECHERCHE INTERNATIONALE

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PCT/FR 03/00438

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
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Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)
CIB 7 A61F

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si réalisable, termes de recherche utilisés)
EPO-Internal

C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie °	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
A	WO 98 02117 A (AESCULAP AG & CO KG ;EISEN GUNTMAR (DE); SCHULTZ ROBERT (DE); WING) 22 janvier 1998 (1998-01-22) revendications 1,3,4; figures ---	1-4, 7-16,18, 19
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[X] Voir la suite du cadre C pour la fin de la liste des documents

[X] Les documents de familles de brevets sont indiqués en annexe

° Catégories spéciales de documents cités:

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"T" document ultérieur publié après la date de dépôt international ou la date de priorité et n'appartenenant pas à l'état de la technique pertinent, mais cité pour comprendre le principe ou la théorie constituant la base de l'invention

"X" document particulièrement pertinent; l'inven tion revendiquée ne peut être considérée comme nouvelle ou comme impliquant une activité inventive par rapport au document considéré isolément

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"&" document qui fait partie de la même famille de brevets

Date à laquelle la recherche internationale a été effectivement achevée	Date d'expédition du présent rapport de recherche internationale
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Nom et adresse postale de l'administration chargée de la recherche internationale	Fonctionnaire autorisé
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Formulaire PCT/ISA/210 (deuxième feuille) (juillet 1992)

C.(suite) DOCUMENTS CONSIDERES COMME PERTINENTS

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RAPPORT DE RECHERCHE INTERNATIONALE

Demande internationale No
PCT/FR 03/00438

Document brevet cité au rapport de recherche		Date de publication	Membre(s) de la famille de brevet(s)		Date de publication
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			IT	1091068 B	26-06-1985
			JP	52064198 A	27-05-1977

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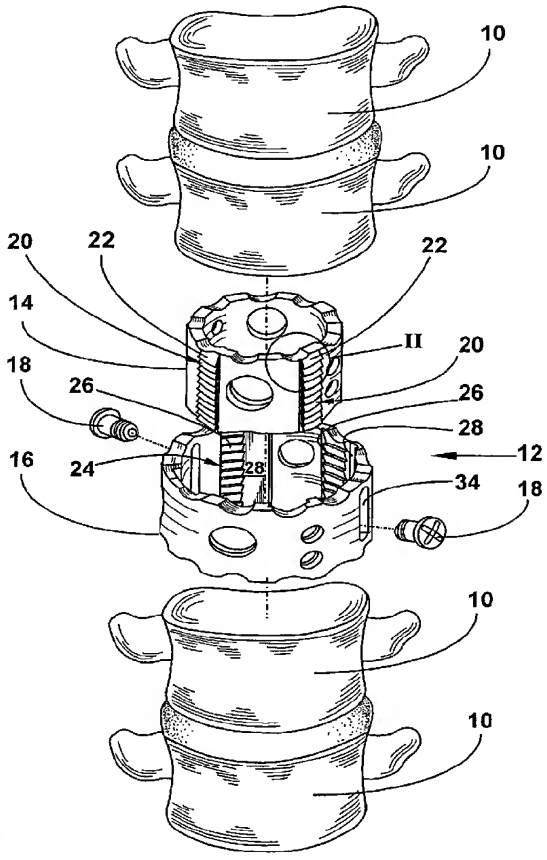
(84) Bestimmungsstaaten *(regional)*: ARIPO-Patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), eurasisches Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches Patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL,

[Fortsetzung auf der nächsten Seite]

(54) Title: VERTEBRAL BODY PLACEHOLDER

(54) Bezeichnung: WIRBELKÖRPERPLATZHALTER



(57) Abstract: The invention relates to a vertebral body placeholder having a cylindrical inner body (14), which can be telescopically inserted into a coaxially arranged, sleeve-shaped outer body (16). A detent device that works in one direction is arranged between the inner body (14) and the outer body (16). A number of detent projections (22) are arranged in succession in an axial direction and form a row (20) of detent projections. A number of detent notches (26) are arranged in succession in an axial direction while corresponding to the row (20) of detent projections. Said detent notches form a row (24) of detent notches that completely or partially accommodate the row (20) of detent projections. The invention also relates to a method for assembling said vertebral body placeholder. The aim of the invention is to create a vertebral body placeholder whose overall height can be easily and reliably adjusted, particularly, during implantation. To this end, a groove (28) for accommodating the row (20) of detent projections without obstructing it is provided next to the row (24) of detent notches.

(57) Zusammenfassung: Gegenstand der Erfindung ist Wirbelkörperplatzhalter mit einem zylindrischen Innenkörper (14), der in einen koaxial angeordneten, hülsenförmigen Aussenkörper (16) teleskopartig einschiebbar ist, wobei zwischen der Innenkörper (14) und dem Aussenkörper (16) eine in eine Richtung wirkencle Rastvorrichtung angeordnet ist, wobei in axialer Richtung mehrere Rastnasen (22) hintereinander angeordnet sind, die eine Rastnasenreihe (20) bilden, und wobei korrespondierend zur Rastnasenreihe (20) in axialer Richtung mehrere Rastkerben (26) hintereinander angeordnet sind, die eine die Rastnasenreihe (20) ganz oder teilweise aufnehmende Rastkerbenreihe (24) bilden und ein Verfahren zu seinem Zusammenbau. Einen Wirbelkörperplatzhalter zu schaffen, dessen Gesamthöhe insbesondere während der Implantation einfach und zuverlässig einstellbar ist wird cladurch erreicht, class neben der Rastkerbenreihe (24) in axialer Richtung eine Nut (28) zur hindernisfreien Aufnahme der Rastnasenreihe (20) vorgesehen ist.

WO 03/096937 A1

PT, RO, SE, SI, SK, TR), OAPI-Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Veröffentlicht:

— *mit internationalem Recherchenbericht*

— *vor Ablauf der für Änderungen der Ansprüche geltenden Frist; Veröffentlichung wird wiederholt, falls Änderungen eintreffen*

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

WIRBELKÖRPERPLATZHALTER

Die vorliegende Erfindung betrifft einen Wirbelkörperplatzhalter gemäß den Merkmalen des Anspruches 1 und ein Verfahren zu seinem Zusammenbau.

Aus dem DE 296 16 778 ist ein Wirbelkörperplatzhalter mit einem zylindrischen Innenkörper bekannt, der in einen koaxial angeordneten, hülsenförmigen Außenkörper teleskopartig einschiebbar ist. Um diesen Wirbelkörperplatzhalter in der gewünschten Position zu fixieren, kann durch den Außenkörper hindurch bis in ein im Innenkörper eingelassenes Gewinde geführt werden. Durch die Anordnung mehrerer Bohrungen und Gewinde in axialer Richtung kann die

Größe dieses Wirbelkörperplatzhalters stufenweise eingestellt werden. Für den operierenden Arzt ist es jedoch sehr mühsam, die gewünschte Größe des Wirbelkörperplatzhalters einzustellen und anschließend diese Schraube in das entsprechende Gewinde einzuführen, insbesondere da der Außen- und der Innenkörper leicht zueinander verrutschen können und da es schon eines gewissen Fingerspitzengefühls bedarf, die Fixierschraube in das entsprechende Gewinde einzuführen.

Aus dem US 5,723,013 Implantat zum Ersatz eines fehlenden Wirbelkörpers bekannt, bei dem an einem inneren Zylinder einige Rastnasen ausgebildet sind, die in entsprechende Rastkerben an einem Außenzylinder eingreifen. Sowohl am inneren Zylinder, als auch am Außenzylinder sind je zwei koaxial verlaufende Schlitze vorgesehen, in die ein Sicherungs- und Fixierelement eingebracht werden kann, sobald beide Zylinder in Deckung gebracht sind. Dabei sind Rastnasen und Rastkerben so ausgelegt, dass der innere Zylinder gegen den Widerstand der Rastnasen aus dem Außenzylinder herausgezogen werden kann.

Während einer Operation ist es aber sehr schwierig zum Einen beide Zylinder in Deckung zu bringen, um das Sicherungselement zu platzieren und zum Anderen ist es schwierig, zur Korrektur der Gesamthöhe des Implantates den Inneren Zylinder gegen die Kraft der Rastnase aus dem Außenzylinder heraus zu ziehen.

Davon ausgehend liegt der vorliegenden Erfindung die Aufgabe zugrunde, einen Wirbelkörperplatzhalter zu schaffen, dessen Gesamthöhe insbesondere während der Implantation einfach und zuverlässig einstellbar ist.

Als technische Lösung dieser Aufgabe wird erfindungsgemäß vorgeschlagen, den eingangs genannten Wirbelkörperplatzhalter dahingehend weiterzubilden, dass neben der Rastkerbenreihe in axialer Richtung eine Nut zur hindernisfreien Aufnahme der Rastnasenreihe vorgesehen ist.

Ein nach dieser technischen Lehre ausgebildeter Wirbelkörperplatzhalter hat den Vorteil, dass es ist möglich, durch Verschwenken des Innenkörpers die jeweiligen Rastnasen aus den jeweiligen Rastkerben heraus und in die Nut zuführen, um anschließend den Innenkörper in axialer Richtung im den Außenkörper hin und her schieben zu können. Dabei werden die Rastnasen ohne eine Widerstand zu leisten entlang der Nut geführt. Durch Zurückschwenken des Innenkörpers werden die Rastnasen wieder in die Rastkerben eingeführt, so dass die Rastvorrichtung nun wieder greift. Hierdurch ist es möglich, einen zu weit herausgezogenen Innenkörper wieder in gewünschter Weise in den Außenkörper hineinzuschieben, oder umgekehrt.

Ein weiterer Vorteil besteht darin, dass vor der Implantation des Wirbelkörperplatzhalters eine Grobeinstellung in beliebiger Weise ohne großen Kraftaufwand möglich ist, und dass anschließend, zum Beispiel nach Platzierung des voreingestellten Wirbelkörperplatzhalters in der Wirbelsäule, durch Verschwenken, axiales Verstellen und Zurückschwenken des Innenkörpers in einfacher Weise eine endgültige Einstellung vorgenommen werden kann.

In einer bevorzugten Weiterbildung sind die Rastnasen und die Rastkerben schräg angeordnet und verlaufen vorzugsweise von der der Nut zugewandten Seite weg nach unten. Dies hat den Vorteil, dass der Wirbelkörperplatzhalter später nicht aus versehen zurückdreht und möglicherweise in sich zusammenrutscht, denn der unter Belastung stehende Wirbelkörperplatzhalter drückt den Innenkörper in die tiefe Seite der Rastkerben, so dass der Innenkörper gegen die auf den Wirbelkörperplatzhalter wirkende Kraft angehoben werden müsste, um verschwenkt zu werden. Hierdurch wird ein hohes Maß an Verschwenksicherheit erreicht.

In einer anderen, bevorzugten Ausführungsform sind äquidistant über den Umfang verteilt vier Rastnasenreihen und vier Rastkerbenreihen vorgesehen. Dies hat den Vorteil, dass der Wirbelkörperplatzhalter durch diese vier Rastvorrichtungen gleichmäßig über den Umfang geführt wird, so dass der Innenkörper nicht verkanten kann.

In einer anderen bevorzugten Ausführungsform ist im Außenkörper ein in axialer Richtung angeordnetes Langloch zur stufenlosen Aufnahme einer Fixierschraube vorgesehen. Dies hat den Vorteil, dass die durch das Langloch hindurchreichende Fixierschraube in jeder gewünschten Stellung des Außenkörpers relativ zum Innenkörper in ein entsprechendes, am Innenkörper vorgesehenes Gewinde eingeschraubt werden kann.

In noch einer anderen, bevorzugten Ausführungsform sind nur zwei, sich gegenüberliegende Rastnasenreihen und Rastkerbenreihen vorgesehen. Hierdurch ist es möglich, den Innenkörper ohne Verschwenken aus dem Außenkörper heraus zu ziehen. In diesem Falle würde über die Rastnasen eine Kraft auf zwei sich gegenüberliegende Stellen des Außenkörpers ausgeübt, so dass der Außenkörper sich für eine kurze Zeit verformt. Dabei ziehen sich die Bereiche des Außenkörpers zwischen den Rastnasenreihen zusammen, während die Rastnasenbereiche solange radial nach außen gedrückt werden, bis die Rastnase die entsprechende Rastkerbe passiert hat. Danach springt der Außenkörper in seine Ursprungsform zurück und der Wirbelkörperplatzhalter ist um eine Rastkerbe vergrößert. Dieser Vorgang kann mehrfach wiederholt werden, bis der Wirbelkörperplatzhalter die gewünschte Größe hat.

Weitere Vorteile des erfindungsgemäßen Wirbelkörperplatzhalters ergeben sich aus der beigefügten Zeichnung und den nachfolgend beschriebenen Ausführungsformen. Ebenso können die vorstehend genannten und die noch weiter ausgeführten Merkmale erfindungsgemäß jeweils einzeln oder in beliebigen Kombinationen miteinander verwendet werden. Die erwähnten Ausführungsformen sind nicht als abschließende Aufzählung zu verstehen, sondern haben vielmehr beispielhaften Charakter. Es zeigt:

Fig. 1 eine Explosionsdarstellung einer Wirbelsäule mit einem erfindungsgemäßen Wirbelkörperplatzhalter;

Fig. 2 eine Ausschnittsvergrößerung des Wirbelkörperplatzhalters gemäß Fig. 1, gemäß Linie II in Fig. 1;

Fig. 3 eine geschnitten dargestellte Draufsicht auf einen Außenkörper des Wirbelkörperplatzhalters gemäß Fig. 1, geschnitten entlang Linie III – III in Fig. 4;

Fig. 4 eine geschnitten dargestellte Seitenansicht des Außenkörpers gemäß Fig. 3, geschnitten entlang Linie IV – IV in Fig. 3.

In Figur 1 ist ein schematischer Darstellung ein Ausschnitt einer menschlichen Wirbelsäule in Explosionsdarstellung abgebildet, bei der zwischen zwei Wirbelkörpern 10 ein zweiteiliger, hohlzylindrischer Wirbelkörperplatzhalter 12 angeordnet ist. Dieser Wirbelkörperplatzhalter 12 umfasst einen kleineren, zylindrischen Innenkörper 14 und einen größeren, ebenfalls zylindrisch ausgebildeten, hülsenförmigen Außenkörper 16, wobei letzterer den Innenkörper 14 passgenau teleskopartig aufnimmt. Durch zwei Fixierschrauben 18 kann der Innenkörper 14 und der Außenkörper 16 vom operierenden Arzt in der gewünschten Position zueinander fixiert werden, um eine optimale Stellung der Wirbelsäule zu erreichen. Dabei ermöglicht ein im Außenkörper 16 angeordnetes Langloch 34 eine Fixierung des Wirbelkörperplatzhalters 12 in jeder beliebigen Stellung. Weitere Einzelheiten betreffend den Wirbelkörperplatzhalter 12 können dem DE 296 16 778 / EP 832 622 entnommen werden, auf die an dieser Stelle voll inhaltlich Bezug genommen wird.

Auf der Außenseite des Innenkörpers 14 sind gleichmäßig über den Umfang verteilt vier Rastnasenreihen 20 vorgesehen, die sich aus mehreren, in axialer Richtung hintereinander angeordneten Rastennasen 22 zusammensetzen. Jede Rastnase 22 hat eine im Wesentlichen radial ausgerichtete Anschlagflanke 32 und eine Gleitflanke (30), wobei der Winkel zwischen der Anschlag- und Gleitflanke zwischen 45 und 90 ° beträgt.

Auf der Innenseite des Außenkörpers 16 sind über den Umfang verteilt vier Rastkerbenreihen 24 vorgesehen, wobei sich jede Rastkerbenreihe 24 aus einer Vielzahl in axialer Richtung hintereinander angeordneter Rastkerben 26 zusammensetzt. Dabei ist die Rastkerbe 26 korrespondierend zu den Rastnasen 22 ausgebildet und weist ebenfalls eine im Wesentlichen radial

ausgerichtete Anschlagflanke und eine im spitzen Winkel hierzu angeordnete Gleitflanke auf. Unmittelbar neben der Rastkerbenreihe 24 ist eine Nut 28 ausgebildet, deren Breite und Tiefe etwas größer als die entsprechenden Rastnasenreihen 20 ausgebildet ist, so dass die Rastnasenreihe 20 in dieser Nut 28 hindernisfrei aufgenommen werden kann.

Wie den Figuren 2 bis 4 detailliert zu entnehmen ist, verlaufen die Rastnasen 22 und die Rastkerben 26 schräg und zwar von der Nut 28 aus nach unten. Berücksichtigt man nun, dass der Wirbelkörperplatzhalter stets unter Belastung ist, so müsste der Innenkörper 14 gegen diese Belastung verschwenkt werden, um aus der einmal eingestellten Position zurück in die Nut zu gelangen. Dies ist normalerweise aufgrund der Belastung des Wirbelkörperplatzhalters nicht möglich, so dass hierdurch eine zuverlässige Verschwenksicherung geschaffen ist.

Während der Implantation des erfindungsgemäße Wirbelkörpers geht der operierende Arzt wie folgt vor:

Durch Verschwenken des Innenkörpers 14 wird die Rastnasenreihe 20 aus dem Eingriff mit der Rastkerbenreihe 24 herausgeführt, so dass die Rastnasenreihe 20 in die Nut 28 gelangt. Nun kann der Innenkörper 14 in beliebiger Weise nach oben oder unten (axial) geschoben werden, um eine vorläufige Grobeinstellung des Wirbelkörperplatzhalters 12 zu erreichen. Ist die gewünschte Position gefunden, so wird der Innenkörper 14 wieder zurückgeschwenkt, so dass die Rastnasenreihe 20 wieder mit der Rastkerbenreihe 24 im Eingriff gelangt. Durch die Anordnung der Rastnasen 22 und Rastkerben 26 liegen beide mit ihren jeweiligen Anschlagflanken aneinander an, so dass ein Hereinrutschen des Innenkörpers 14 in den Außenkörper 16 zuverlässig verhindert wird. Nachdem der Wirbelkörperplatzhalter 12 an der gewünschten Stelle in die Wirbelsäule eingesetzt ist, kann der operierende Arzt diesen Vorgang wiederholen, um den Wirbelkörperplatzhalter 12 endgültig in die gewünschte Position zu bringen.

In einer anderen, hier nicht dargestellten Ausführungsform sind nur zwei Rastnasen- und Rastkerbenreihen vorgesehen. Insbesondere bei dieser Ausführungsform (auch bei der dargestellten Ausführungsform) kann der operierende Arzt den Innenkörper 14 nach der Grobeinstellung zwecks Feineinstellung nun weiter aus dem Außenkörper 16 herausziehen. Dabei gleiten die jeweiligen Rastnasen 22 und Rastkerben 26 mit ihren Gleitflanken aneinander so lange, bis die Rastnase 22 in die nächstliegende Rastkerbe 26 hineinspringt. Auf diese Art und Weise kann der Wirbelkörperplatzhalter 12 in beliebiger Weise eingestellt werden, ohne dass die Gefahr eines Zurückgleitens gegeben ist. In dieser Position kann der Wirbelkörperplatzhalter 12 durch die Fixierschraube gesichert werden.

Bezugszeichenliste:

10	Wirbelkörper
12	Wirbelkörperplatzhalter
14	Innenkörper
16	Außenkörper
18	Fixierschraube
20	Rastnasenreihe
22	Rastnase
24	Rastkerbenreihe
26	Rastkerbe
28	Nut

Ansprüche:

1. Wirbelkörperplatzhalter mit einem zylindrischen Innenkörper (14), der in einen koaxial angeordneten, hülsenförmigen Außenkörper (16) teleskopartig einschiebbar ist, wobei zwischen dem Innenkörper (14) und dem Außenkörper (16) eine in eine Richtung wirkende Rastvorrichtung angeordnet ist, wobei in axialer Richtung mehrere Rastnasen (22) hintereinander angeordnet sind, die eine Rastnasenreihe (20) bilden, und wobei korrespondierend zur Rastnasenreihe (20) in axialer Richtung mehrere Rastkerben (26) hintereinander angeordnet sind, die eine die Rastnasenreihe (20) ganz oder teilweise aufnehmende Rastkerbenreihe (24) bilden,
d a d u r c h g e k e n n z e i c h n e t,
dass neben der Rastkerbenreihe (24) in axialer Richtung eine Nut (28) zur hindernisfreien Aufnahme der Rastnasenreihe (20) vorgesehen ist.

2. Wirbelkörperplatzhalter nach Anspruch 1,
d a d u r c h g e k e n n z e i c h n e t,
dass die Rastnasen (22) und dazu korrespondieren die Rastkerben (26) schräg angeordnet sind.

3. Wirbelkörperplatzhalter nach Anspruche 2,
d a d u r c h g e k e n n z e i c h n e t,
dass die Rastnasen (22) und die Rastkerben (26) von der der Rastkerbenreihe () angrenzenden Seite schräg abfallen, um so ein etwaiges Lösen zu hemmen.

4. Wirbelkörperplatzhalter nach einem der vorangehenden Ansprüche,
d a d u r c h g e k e n n z e i c h n e t,
dass äquidistant über den Umfang verteilt zwei oder vier Rastnasenreihen (20) und zwei oder vier Rastkerbenreihen (24) vorgesehen sind.

5. Wirbelkörperplatzhalter nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass im Aussenkörper (16) ein in axialer Richtung angeordnetes Langloch (34) zur stufenlosen Aufnahme einer Fixierschraube (18) vorgesehen ist.

6. Verfahren zum Zusammenbau eines Wirbelkörperplatzhalters gemäß einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass der Innenkörper (14) in den Außenkörper (16) eingesteckt wird, wobei die Rastnasenreihe (20) solange in der Nut (28) geführt wird, bis die gewünschte Position erreicht ist, und dass anschließend der Innenkörper (14) gegenüber dem Außenkörper (16) verschwenkt wird, so dass die Rastnasenreihe (20) mit der Rastkerbenreihe (24) in Eingriff gelangt.

7. Verfahren nach Anspruch 6, dadurch gekennzeichnet, dass zum Verändern der Bauhöhe des Wirbelkörperplatzhalters der Innenkörper (14) so weit gegenüber dem Außenkörper (16) geschwenkt wird, bis die Rastnasenreihe (20) in der Nut (28) ist, bevor der Innenkörper (14) durch verschieben mit in der Nut (28) geführter Rastnasenreihe (20) in die gewünschte Position gebracht wird, und dass anschließend der Innenkörper (14) in seine Anfangsposition zurückgeschwenkt wird, so dass die Rastnasen (22) wieder in die Rastkerben (26) eingreifen.

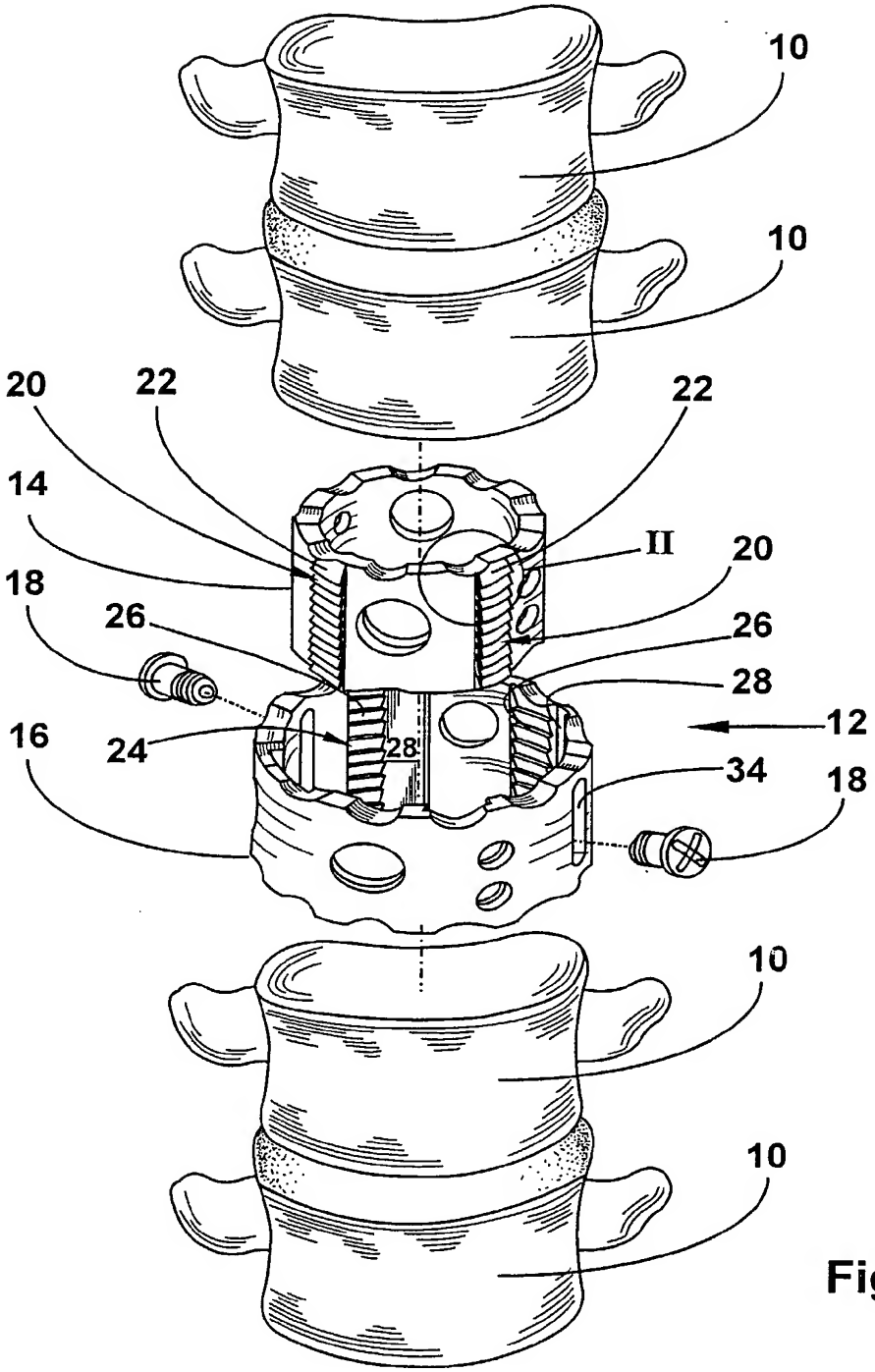


Fig. 1

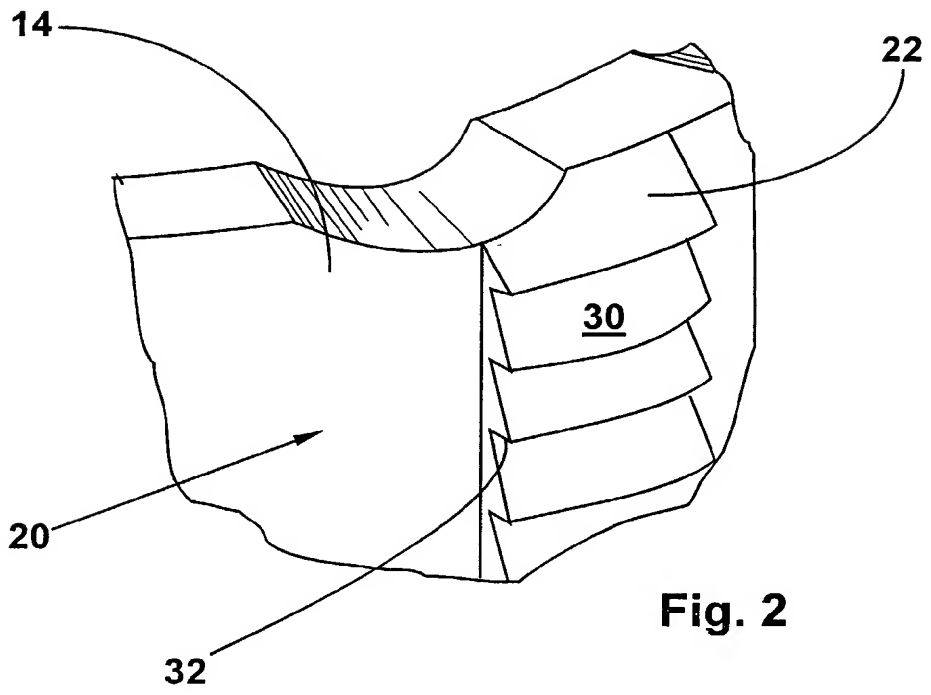


Fig. 2

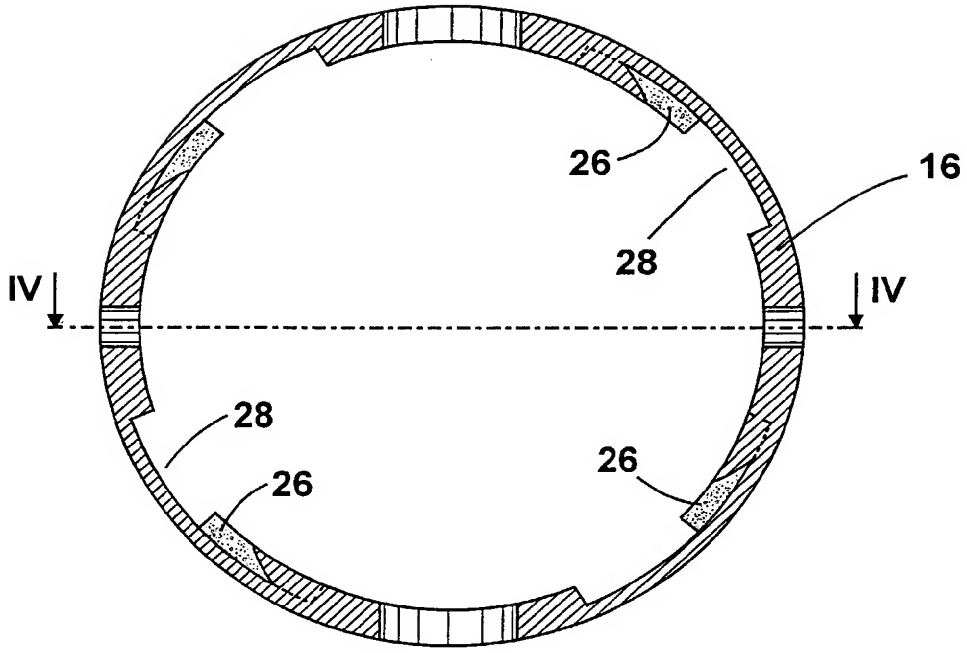


Fig. 3

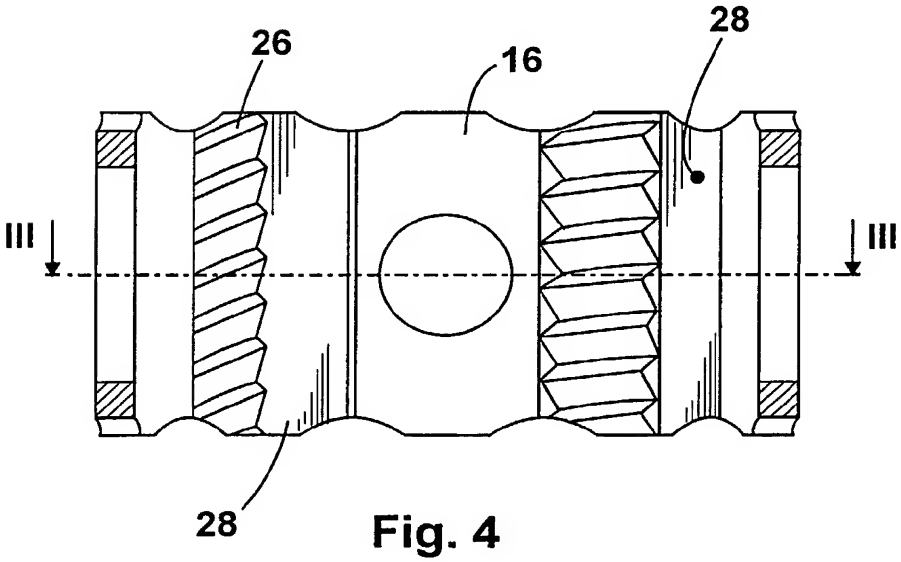


Fig. 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/DE 03/01607

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/30 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 080 703 A (HOWMEDICA OSTEONICS CORP) 7 March 2001 (2001-03-07) paragraphs '0039!-'0045!; figures 1-14 ---	1-4,6,7
X	WO 00 23013 A (BENOIT ALFRED ;LAENG BRUNO (CH); SYNTHES AG (CH); SYNTHES USA (US)) 27 April 2000 (2000-04-27) claims 1-5; figures	1,4,6,7
Y	---	5
Y	WO 99 63913 A (SURGICARFT LTD ;UPADHYAY SHANTI (GB); EVANS SAMUEL LEWIN (GB)) 16 December 1999 (1999-12-16) figures 1,5 page 7, paragraphs 3,4	5
A	-----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
2 October 2003	10/10/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Stach, R

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/DE 03/01607

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
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			CA	2317095 A1	02-03-2001
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			JP	2001104325 A	17-04-2001
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			AU	738199 B2	13-09-2001
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			JP	2002527195 T	27-08-2002
			US	2002161441 A1	31-10-2002
			ZA	9906494 A	18-04-2000
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			WO	9963913 A2	16-12-1999

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/DE 03/01607

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 7 A61F2/30 A61F2/44

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
IPK 7 A61F

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	EP 1 080 703 A (HOWMEDICA OSTEONICS CORP) 7. März 2001 (2001-03-07) Absätze '0039!-'0045!; Abbildungen 1-14	1-4,6,7
X	WO 00 23013 A (BENOIT ALFRED ;LAENG BRUNO (CH); SYNTHES AG (CH); SYNTHES USA (US)) 27. April 2000 (2000-04-27) Ansprüche 1-5; Abbildungen	1,4,6,7
Y		5
Y	WO 99 63913 A (SURGICARFT LTD ;UPADHYAY SHANTI (GB); EVANS SAMUEL LEWIN (GB)) 16. Dezember 1999 (1999-12-16) Abbildungen 1,5 Seite 7, Absätze 3,4	5
A		1

☐ Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

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° Besondere Kategorien von angegebenen Veröffentlichungen :
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Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
2. Oktober 2003	10/10/2003

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Stach, R

Formblatt PCT/ISA/210 (Blatt 2) (Juli 1992)

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen
PCT/DE 03/01607

Im Recherchenbericht angeführtes Patentdokument		Datum der Veröffentlichung	Mitglied(er) der Patentfamilie		Datum der Veröffentlichung
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			CA	2317095 A1	02-03-2001
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			US	2002161441 A1	31-10-2002
			ZA	9906494 A	18-04-2000
WO 9963913	A	16-12-1999	AU	4158599 A	30-12-1999
			WO	9963913 A2	16-12-1999

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(72) Inventor; and

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(74) Agent: **LOTTI, Giorgio**; c/o Ing. Barzanó & Zanardo, Milano S.p.A., C.so Vittorio Emanuele II, 61, I-10128 Torino (IT).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

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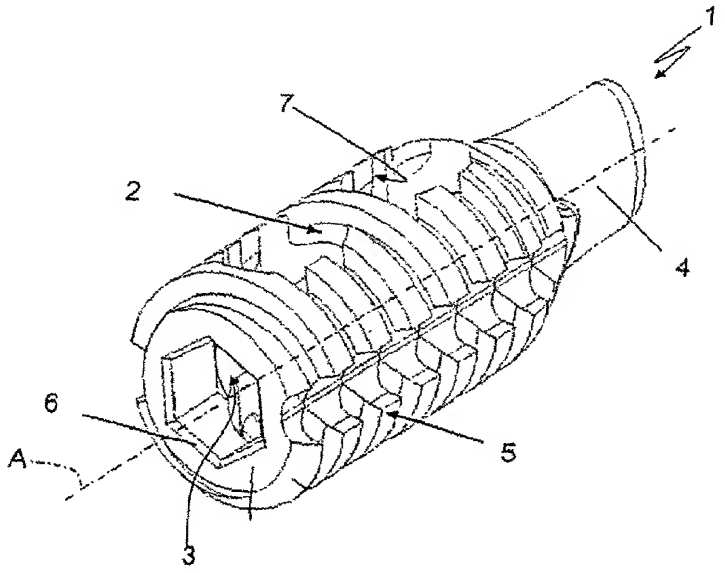
Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

[Continued on next page]

(54) Title: DEVICE FOR INTERSOMATIC STABILIZATION USING A MINI-INVASIVE APPROACH



(57) Abstract: A device (1) for intersomatic stabilization using a mini-invasive approach, which is designed to be inserted between two contiguous vertebrae to keep them at a distance from one another and has a substantially cylindrical body (2) extending along a longitudinal axis (A), and a thread (5) external to and fixed to the body (2) itself; a head end (4) having a cross section that increases along the axis (A) is provided at one end of the body (2) for dilating the intervertebral space as advance of the end (4) itself in the intervertebral space proceeds until there is created with the thread (5) a seat for the subsequent advance of the device (1) having stabilizing function.

WO 03/009786 A1

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DEVICE FOR INTERSOMATIC STABILIZATION USING A MINI-INVASIVE APPROACH.

DESCRIPTION

The present invention relates to a device for intersomatic stabilization using a mini-invasive approach designed to be inserted between two contiguous vertebrae for keeping the two vertebrae at a distance apart from one another and for favouring their intersomatic fusion.

In degenerative discopathies and other similar conditions that lead to the collapse of an intervertebral disc with a consequent vertebral instability and co-presence of backache, there is known the use of devices for intersomatic stabilization designed to reconstitute the intervertebral space and to restore, simultaneously, spinal stability, which is fully obtained following upon completion of a valid bone fusion between the two vertebrae concerned.

Known devices for intersomatic stabilization, which are generally referred to as "cages", may be of the screwed type or else of the impact type and

entail the use of further tools for the preparation of a threaded seat for the cage and for maintaining the correct intervertebral distance during insertion of the device itself, at the end of which preparatory step a certain amount of homologous or autologous bone is normally inserted for the purpose of facilitating intersomatic fusion.

Once fusion is achieved, the two contiguous vertebrae are perfectly stable, and the implanted cage is completely integrated with attainment of spinal stability, as well as disappearance of pain.

Known surgical techniques resort to different modes of access for the implantation of the above-mentioned devices for intersomatic stabilization. Various modes of access are in fact practicable: posterior, lateral or anterior. These are chosen according to the particular condition to be treated and the inclinations and modes of operating of the surgeon.

Devices for intersomatic stabilization of the type described above and the possibility afforded by them for being inserted only through the customary routes of access pose a number of problems, which are due also to the dimensions of the devices

normally commercially available.

In fact, the above devices may cause a significant destruction of the bone stock, both at the level of the compact bone of the discs and at the level of the laminae and of the articular surfaces. Added to this is the further negative aspect that the two contiguous vertebral bodies, which are disadvantageously damaged in their integrity, both anterior and posterior, on account of the intervention of preparation and insertion of the device, also lose their intrinsic stability.

The purpose of the present invention is to provide a device for intersomatic stabilization using a mini-invasive approach, which presents structural and functional characteristics such that the implantation proves significantly less invasive and, especially, such as to guarantee the almost absolute integrity of laminae and articular processes, thus solving the problems described above.

According to the present invention, there is provided a device for intersomatic stabilization using a mini-invasive approach, which is designed to be inserted between two contiguous vertebrae to keep

them at a distance from one another and which comprises a substantially cylindrical body extending along a longitudinal axis and a thread external to and fixed to the body itself. The said device is characterized in that it comprises a head end, which is fixed to the body and defined by a solid of revolution of cross section that increases along the axis, the end being designed to dilate the intervertebral space as advance of the end itself proceeds in the intervertebral space until there is created by the thread a seat for the subsequent advance of the device with stabilizing function.

The invention will now be described with reference to the attached drawings, which illustrate a non-limiting example of embodiment thereof and in which:

- Figure 1 is a rear perspective view of a first preferred embodiment of the device for intersomatic stabilization using a mini-invasive approach according to the present invention;

- Figure 2 is a front perspective view of the device of Figure 1;

- Figure 3 is a cross-sectional view of the device of Figure 1 taken according to an axial plane

of the device itself; and

- Figure 4 illustrates, in side elevation, a second preferred embodiment of the device of Figure 1.

With reference to Figures 1, 2 and 3, the reference number 1 designates as a whole a device for intersomatic stabilization using a mini-invasive approach designed to be inserted between two contiguous vertebrae for keeping the two vertebrae themselves at a distance apart from one another and for favouring their subsequent intersomatic fusion.

The device 1 comprises a hollow cylindrical body 2, which extends along a respective major longitudinal axis A and is provided with an internal through cavity 3, and a shaped head 4 set at one end of the body 2. The body 2 is moreover provided with a threaded external surface 5, the thread possibly having even more than one start, which extends throughout the body 2 itself starting from the head 4 and enables screwing of the device 1 in the space between the two vertebrae referred to above.

The cavity 3 presents, in a cross section transverse to the axis A, a substantially cylindrical shape, and is provided with a slot 6

with a hexagonal cross section defining a seat for transmission of the tightening torque to the device 1 by a manoeuvring tool, as well as with a further seat 8 set along the axis A and inside the head 4, the said seat 8 being designed to cause the device 1 and the above-mentioned manoeuvring tool to be integrally fixed together.

The cavity 3 is moreover provided with four through holes 7, which are made through the surface 5 to set the cavity 3 in communication with the outside world and are aligned in twos along the axis A and aligned in twos in a direction transverse to the axis A.

The surface 5 has an external diameter that is practically constant along the entire axis A, except for the area immediately adjacent to the slot 6, and the area immediately contiguous to the head 4, which, instead, is tapered towards the head 4 itself and is made in such a way as to be self-tapping, according to technologies that are already known and applied in mechanical engineering.

The head 4 has the task, during insertion of the device 1 between the aforementioned two vertebrae, of appropriately dilating the

intervertebral space so as to enable the subsequent screwing of the device 1 itself, and is defined by a solid of revolution of increasing section having a substantially elliptical cross section and a thickness S, which varies as the angular position of the device 1 about the axis A varies.

The head 4 is made so as to enable its insertion in an intervertebral space of limited height and then, by means of a rotation through 90 degrees, to increase the intervertebral space itself up to the height necessary for the surface 5 to be able to start gripping in the bone of the aforementioned two vertebrae, creating in the bone itself a seat for the subsequent advance of the device 1 having stabilizing function.

The device 1 described above renders unnecessary both the dilators used before the introduction of all the cages mentioned above in the introduction and the positioning and maintenance *in situ* of dilators or spacers that guarantee maintenance of the intersomatic distance in the step of milling and threading of the vertebral bodies prior to introduction of the threaded cages.

The resultant of these two advantages is the

availability of a cage having a dilating head 4, which guarantees, during the step of tapping, a correct spontaneous positioning of the head 4 itself between the two vertebral bodies, the said relative distance being maintained as the advance of the head 4 of the body 2 proceeds.

In other words, the device 1 can enable provision of an intersomatic arthrodesis with posterior or monolateral intraforaminal bilateral mini-invasive approach, and, finally, positioning by posterior or posterolateral (intraforaminal) route of the device 1 will not cause any destruction or destabilization of the posterior compartment, providing, instead, an extremely valid intersomatic arthrodesis.

The embodiment illustrated in Figure 4 relates to a device 1' similar to the device 1, from which the device 1' differs in the respect that the head 4 does not have a substantially elliptical cross section, but an ogival shape, and the progressive distancing of the two aforementioned vertebrae is consequently obtained by impacting along the axis A of the body 2.

The device 1' has an action of impact, unlike

the device 1 which, instead, has a lever-type dilating action, nevertheless affording all the advantages provided by the device 1.

It is to be understood that the invention is not limited to the embodiments described and illustrated herein, which are to be considered as examples of embodiment of the device for intersomatic stabilization using a mini-invasive approach, the said device being liable to further modifications as regards the shapes and arrangement of parts, and as regards details of construction and assembly.

CLAIMS

1. A device (1,1') for intersomatic stabilization using a mini-invasive approach designed to be inserted between two contiguous vertebrae to keep them at a distance from one another, and comprising a substantially cylindrical body (2), which extends along a longitudinal axis (A), and a thread (5) external to and fixed to the body (2) itself, the said device (1,1') being characterized in that it comprises a head end (4), which is fixed to the body (2) and defined by a solid of revolution having a cross section that increases along the axis (A), the end (4) being designed to dilate the intervertebral space as advance of the end (4) itself proceeds in the intervertebral space until there is created with the thread (5) a seat for the subsequent advance of the device (1,1') having stabilizing function.

2. The device according to Claim 1, characterized in that said head end (4) has an elliptical cross section so as to present a thickness (S), which varies as an angular position of the body (2) about the said axis (A) varies.

3. The device according to Claim 1, characterized in that said head end (4) has an increasing oval cross section so as to dilate the intervertebral space as its advance in the intervertebral space proceeds.

4. The device according to Claim 1, characterized in that said body (2) is provided with a seat (6) for angular coupling of the device (1,1') itself with a manoeuvring tool, as well as with a further seat (8) designed to cause the device (1,1') and the said manoeuvring tool to be integrally fixed together.

5. The device according to Claim 4, characterized in that said body (2) comprises an internal cavity (3) extending along the axis (A) and delimited at its own opposite ends by the said two seats (6, 8).

6. The device according to Claim 5, characterized in that the cavity (3) is provided with four through holes (7), which are made through said thread (5) to set the cavity (3) itself in communication with the outside world, and which are aligned in twos along the axis (A) and aligned in twos in a direction transverse to the axis (A) itself.

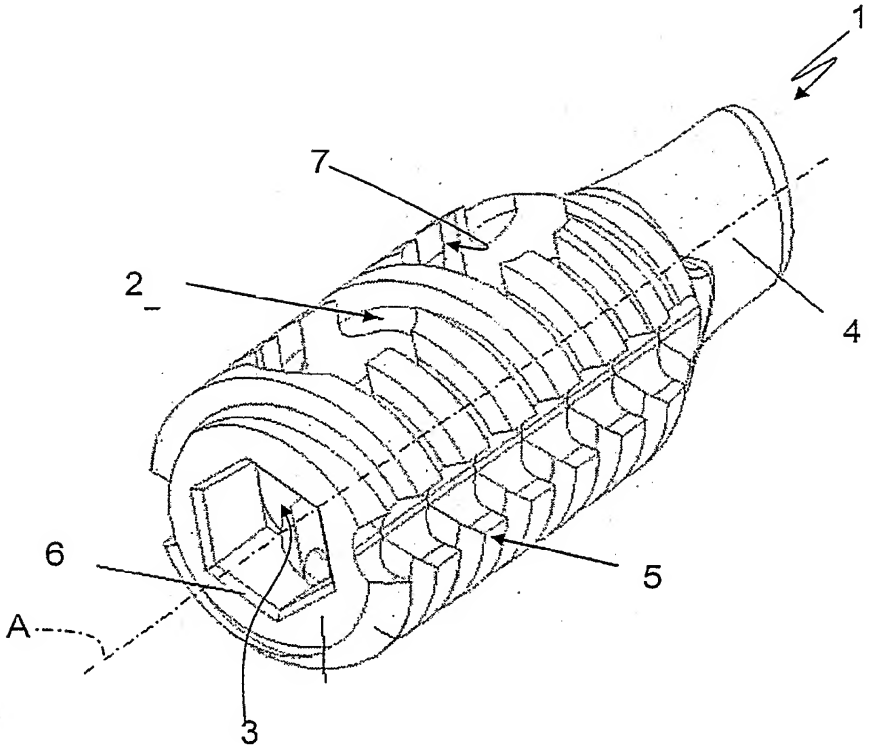


Fig. 1

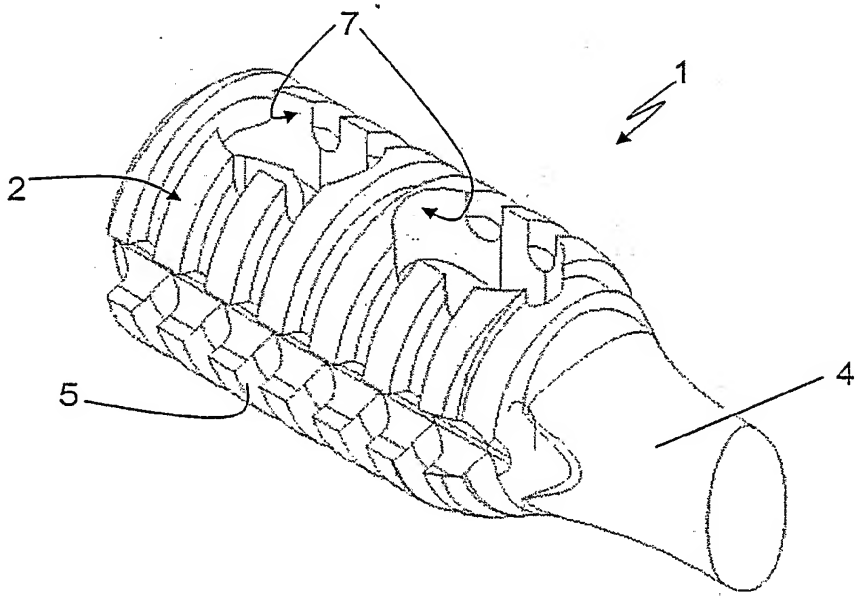


Fig. 2

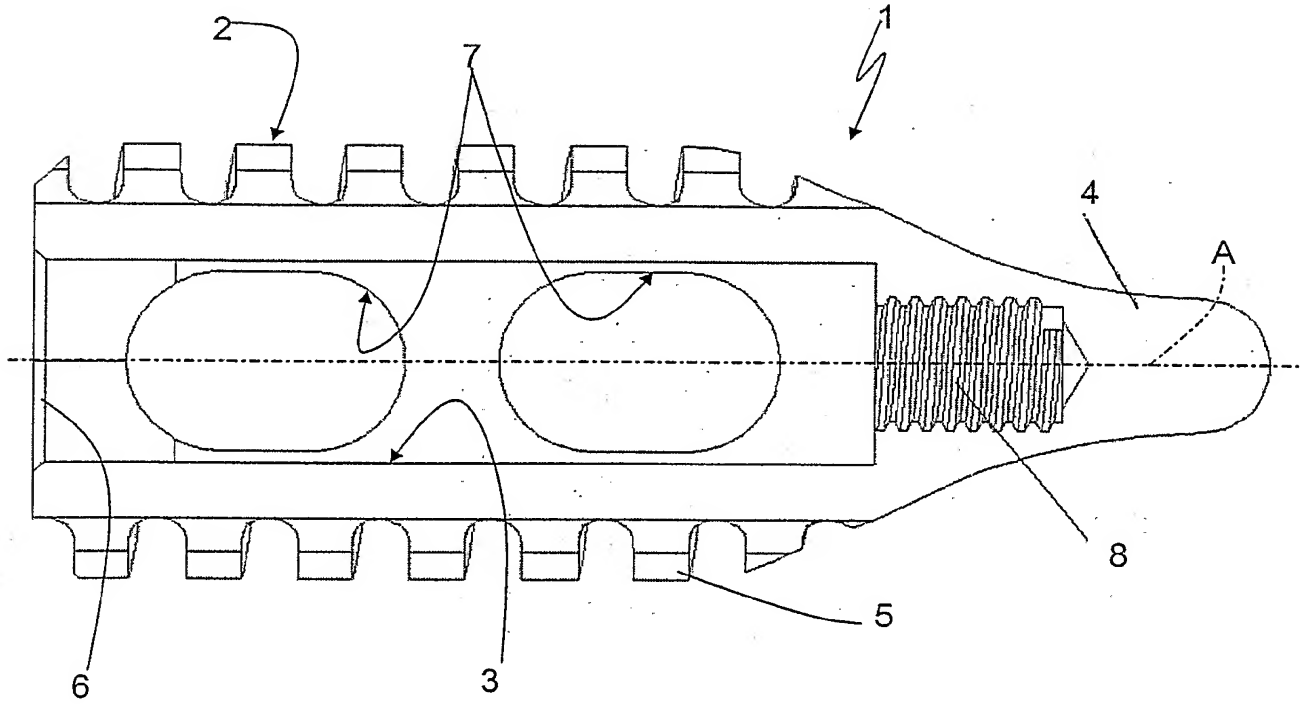


Fig. 3

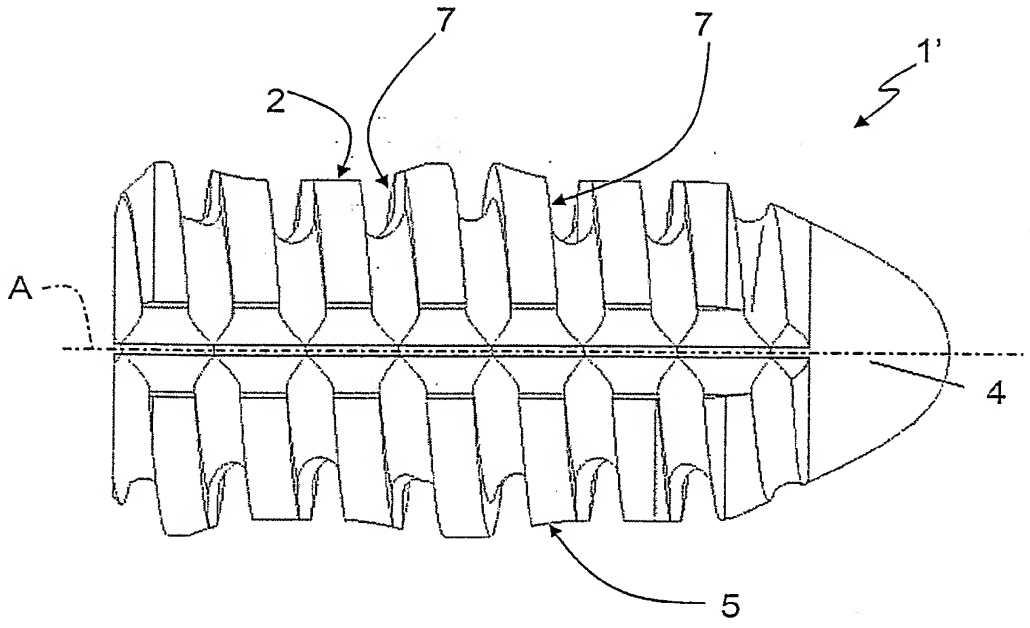


Fig. 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 02/08238

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 093 207 A (PISHARODI MADHAVAN) 25 July 2000 (2000-07-25) claims 9,10; figures column 7, line 20 - line 37	1,4,5
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[X] Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
21 November 2002	28/11/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Stach, R

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 02/08238

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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Information on patent family members

International Application No
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(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

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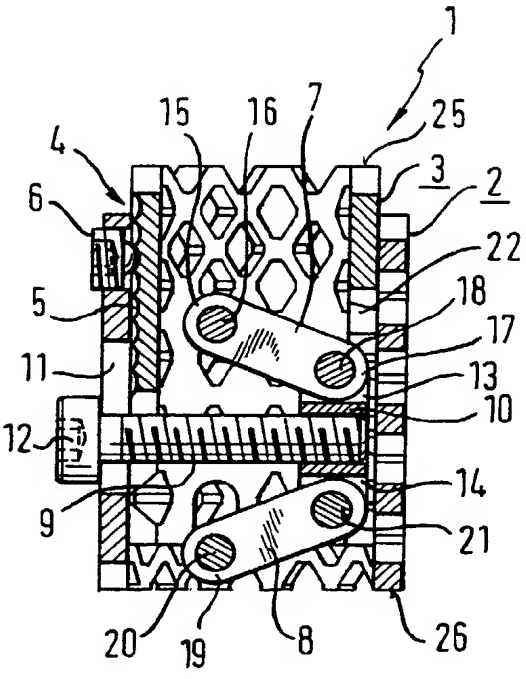
(81) Bestimmungsstaaten *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Bestimmungsstaaten *(regional)*: ARIPO-Patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), eurasisches Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches Patent (AT, BE, BG, CH, CY, CZ, DE,

[Fortsetzung auf der nächsten Seite]

(54) Title: SPACER HAVING A VARIABLE AXIAL LENGTH

(54) Bezeichnung: PLATZHALTER MIT VERÄNDERBARER AXIALER LÄNGE



(57) Abstract: The invention relates to a spacer (1) to be inserted between two vertebral bodies which has a variable axial length. The spacer is provided with a cylinder-shaped first element (2) and a second element (3) guided therein that can be axially displaced relative to the first element, for adjusting an overall length. Adjustment during surgery can be facilitated when the two elements (2, 3) are interlinked by a lever (7, 8), the one fulcrum (16) of the lever being functionally linked with the one element (3) and the other fulcrum (18) being functionally linked with the other element (2).

(57) Zusammenfassung: Es wird ein Platzhalter (1) zum Einsetzen zwischen zwei Wirbelkörper mit einer veränderbaren axialen Länge geschaffen. Der Platzhalter weist ein hülsenartiges erstes Teil (2) und ein in diesem geführtes und in axialer Richtung relativ zum ersten Teil bewegbares zweites Teil (3) zum Einstellen einer Gesamtlänge auf. Damit die Einstellbarkeit während des Operieren erleichtert wird, sind die beiden Teile (2, 3) durch einen Hebel (7, 8) untereinander verbunden, wobei der eine Drehpunkt (16) des Hebels mit dem einen Teil (3) und der andere Drehpunkt (18) wirkungsmässig mit dem anderen Teil (2) verbunden ist.

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DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI-Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Erklärung gemäß Regel 4.17:

— *Erfindererklärung (Regel 4.17 Ziffer iv) nur für US*

Veröffentlicht:

— *mit internationalem Recherchenbericht*

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

Platzhalter mit veränderbarer axialer Länge

Die Erfindung betrifft einen Platzhalter zum Einsetzen zwischen zwei Wirbelkörper mit einer veränderbaren axialen Länge, der ein hülsenartiges erstes Teil und ein in diesem geführtes und in axialer Richtung relativ zum ersten Teil bewegbares zweites Teil zum Einstellen einer Gesamtlänge aufweist.

Ein derartiger Platzhalter ist aus EP 0 977 528 A 1 bekannt. Bei diesem werden die beiden Teile in der zusammengeschobenen Stellung zwischen zwei Wirbelkörper eingefügt und dann auf die gewünschte Länge von Hand auseinandergezogen und in der auseinandergezogenen Stellung dann arretiert.

Aufgabe der Erfindung ist es, einen Platzhalter der eingangs beschriebenen Art zu schaffen, bei dem der Operateur das Einstellen auf die gewünschte Länge auf einfachste Weise bewerkstelligen kann.

Diese Aufgabe wird durch einen Platzhalter der eingangs beschriebenen Art gelöst, der dadurch gekennzeichnet ist, daß

die beiden Teile durch einen Hebel miteinander verbunden sind, dessen einer Drehpunkt mit dem einen Teil und dessen anderer Drehpunkt mit dem anderen Teil verbunden ist.

Weiterbildungen der Erfindung sind in den Unteransprüchen gekennzeichnet.

Weitere Merkmale und Zweckmäßigkeiten der Erfindung ergeben sich aus der Beschreibung von Ausführungsbeispielen anhand der Figuren. Von den Figuren zeigen:

Fig. 1 eine Seitenansicht des Platzhalters in zusammengezogener Stellung;

Fig. 2 einen Schnitt entlang der Linie II/II in Fig. 1;

Fig. 3 den gleichen Schnitt wie Fig. 2, bei dem jedoch der Platzhalter auf seine Maximallänge auseinander gezogen ist;

Fig. 4 eine Draufsicht auf den in Fig. 1 gezeigten Gegenstand;

Fig. 5 eine zweite Ausführungsform in einer der Schnittdarstellung II/II entsprechenden Darstellung in auseinandergezogener Stellung;

Fig. 6 die zweite Ausführungsform in zusammengezogener Darstellung;

Fig. 7 einen Schnitt durch eine weitere Ausführungsform.

Wie am besten aus Fig. 1 ersichtlich ist, umfaßt ein Platzhalter 1 ein hülsenartiges erstes Teil 2 und ein in diesem geführtes hülsenartiges zweites Teil 3. Die beiden Teile können maximal ineinander geschoben werden, wie es in Fig. 1 und 2 gezeigt ist, und auf eine maximale Länge auseinanderbewegt werden, wie dies in Fig. 3 gezeigt ist.

Wie aus den Figuren 1 bis 3 ersichtlich ist, weist das innere zweite Teil 3 auf seiner dem äußeren ersten Teil 2 zugewandten Außenwand einen sich in axialer Richtung erstreckenden Abschnitt mit einer Rasterung 4 mit einer Mehrzahl von in axialer Richtung benachbart zueinander angeordneten und aneinander grenzenden Vertiefungen 5 und das äußere erste Teil 2 ein mit der Rasterung in Eingriff bringbares Feststellteil 6 auf. Das Feststellteil dient dazu, die beiden Teile in einer gewünschten Position zueinander zu arretieren.

Wie am besten aus den Figuren 2 und 4 ersichtlich ist, weist der Platzhalter 1 eine Hebeleinrichtung zum Verstellen der axialen Position der beiden Teile zueinander auf. In der ersten Ausführungsform umfaßt diese einen ersten Hebelarm 7, einen zweiten Hebelarm 8, eine Stellschraube 9 und eine Gewindehülse 10. Wie am besten aus Fig. 2 ersichtlich ist, weist das äußere erste Teil 2 seitlich eine Ausnehmung 11 auf, deren seitliche Ausdehnung kleiner ist als der Durchmesser des Kopfes 12 der Stellschraube 9, wie dies am besten aus Fig. 1 ersichtlich ist. Die Stellschraube 9 ist in der in Fig. 2 ersichtlichen Weise in den Innenraum der hülsenartigen Teile quer zur Axialrichtung eingefügt. Die Gewindehülse 10 ist auf der Schraube aufgeschraubt. Sie weist an ihren beiden sich in axialer Richtung der Hülse erstreckenden beiden Seiten Ansätze 13, 14 auf. Der Ansatz 13 dient zur Verbindung mit dem ersten Hebelarm 7. Der Hebelarm ist mit seinem ersten

Ende 15 mittels einer an zwei gegenüberliegenden Stellen der Wandung des zweiten Teiles 3 lagernden Welle 16 um diese schwenkbar gelagert. Die Welle erstreckt sich senkrecht zur Längsachse des Platzhalters. Der erste Hebelarm ist an seinem der Verbindung mit der Welle 16 gegenüberliegenden zweiten Ende 17 über einen Bolzen bzw. eine Welle 18 mit dem Ansatz 13 um die Welle 18 schwenkbar verbunden. Der Bolzen bzw. die Welle 18 erstreckt sich parallel zur Welle 16.

Wie in Fig. 2 dargestellt ist, ist der zweite Hebelarm 8, um die Stellschraube 9 gesehen, symmetrisch zum ersten Hebelarm 7 ausgebildet bzw. angeordnet. An seinem ersten Ende 15 entsprechend gegenüber liegenden Ende 19 ist der Hebelarm über eine Welle 20 um diese schwenkbar gelagert. Die Welle 20 ist in den einander gegenüber liegenden Seitenwandungen des ersten Teiles 2 seitlich gelagert und erstreckt sich parallel zur Welle 16. An seinem dem Ende 19 gegenüber liegenden Ende ist der zweite Hebelarm mittels eines Bolzens bzw. einer Welle 21 mit dem Ansatz 14 um die Welle 21 schwenkbar verbunden.

Wie aus den Figuren 1 und 2 ersichtlich ist, ist die Ausnehmung 11 als ein sich in seiner Richtung parallel zur Längsachse des Platzhalters erstreckendes Langloch ausgebildet. Das Langloch ist so positioniert, daß die Stellschraube 9 in diesem so weit hin und her bewegbar ist, daß die Schraube von der in Fig. 2 gezeigten zusammengefahrenen Position bis zu der in Fig. 3 gezeigten auseinanderbewegten Position im Langloch hin und her bewegbar ist.

Im Betrieb wird der Platzhalter in der in Fig. 2 gezeigten zusammen gezogenen Stellung mit minimaler Länge in axialer Richtung zwischen die Wirbel eingesetzt. Dann wird die Länge durch Eingreifen mittels eines Schraubendrehers in eine ent-

sprechende Schlitz- bzw. Sechskantöffnung des Kopfes 12 der Stellschraube 9 dadurch auf eine gewünschte Länge verstellt, daß die Stellschraube 9 so gedreht wird, daß die Gewindehülse 10 aus der in Fig. 2 gezeigten äußersten Position, in der sich die Gewindehülse am freien Ende der Stellschraube 9 befindet, zum Kopf hin bewegt wird. Dabei werden die beiden Hebel 7,8 aus ihrer zusammengefahrenen Position in eine in Fig. 3 gezeigte maximal gestreckte Position verfahren. Auf diese Weise werden die beiden hülsenartigen Teile 2 und 3 aus der in Fig. 2 gezeigten zusammen gezogenen Stellung in die in Fig. 3 gezeigte expandierte Stellung oder jede Zwischenstellung bewegt. Durch die Schraubenführung zwischen Stellschraube 9 und Gewindehülse 10 bleiben die beiden Teile zunächst in der durch das Drehen der Stellschraube 9 erreichten Stellung. Sobald diese Stellung als endgültig angesehen wird, erfolgt ein vollständiges Arretieren durch Anziehen der das Feststellteil 6 bildenden Arretierschraube, die zu diesem Zweck in eine Vertiefung 5 der Rasterung 4 eingreift.

Bei der oben beschriebenen Ausführungsform ist die Länge der Stellschraube 9 so gewählt, daß die Stellschraube mit ihrem freien Ende in den hohlen Innenraum des zweiten Teiles 3 hineinreicht, ohne mit der gegenüber liegenden Wandung des zweiten Teiles 3 in Eingriff zu gelangen, so daß keine Behinderung der Bewegung des zweiten Teiles 3 erfolgt. Wie in den Figuren gezeigt ist, weist das zweite Teil 3 bevorzugt eine Ausnehmung 22 auf, die als Langloch ausgebildet ist, welches sich in seiner Längsrichtung parallel zur Längsachse des Platzhalters erstreckt und die in ihrer Länge und Breite so ausgebildet ist, daß das freie Ende der Stellschraube 9 mit der darauf gleitenden Gewindehülse 10 und den beiden Ansätzen 13 und 14 und den damit verbundenen Enden der beiden Hebelarme 7 und 8 bei der in den Figuren 2 und 3 gezeigten Hinund-

her-Bewegung in dem Langloch frei hin und her bewegen können. Auf diese Weise wird erreicht, daß die Stellschraube 9 eine größere Länge aufweisen kann, wodurch der Weg der Gewindehülse 10 vergrößert und damit die Expansionsmöglichkeit der beiden Teile bzw. des Platzhalters vergrößert wird.

In einer in den Figuren 5 und 6 gezeigten abgewandelten Ausführungsform sind das zweite Teil 3, die Stellschraube 9, der erste Hebelarm 7, der Ansatz 13 und die beiden Wellen 16 und 18 in gleicher Weise ausgebildet wie die entsprechenden Elemente in der ersten Ausführungsform.

In der zweiten Ausführungsform ist anstelle des Langloches 11 ein die Stellschraube führendes Rundloch 23 in der Wandung des ersten Teiles 2' vorgesehen, welches in seinem Durchmesser so gewählt ist, daß die Stellschraube in diesem Loch drehbar geführt ist. Die Gewindehülse 10' weist nur einen Ansatz 13 auf.

Im Betrieb erfolgt das Einstellen zwischen der in Fig. 6 gezeigten zusammengeschobenen Stellung und der in Fig. 5 gezeigten expandierten Stellung wie bei der ersten Ausführungsform durch Drehen der Stellschraube 9 derart, daß die Gewindehülse 10' aus der in Fig. 6 gezeigten äußersten Stellung am freien Ende zum Kopf hin soweit verschraubt wird, bis die Expansion auf ein gewünschtes Maß erfolgt ist bzw. der Hebel 7 nahezu in die vertikale Position bewegt ist. Das abschließende Arretieren erfolgt wie beim ersten Ausführungsbeispiel durch Festziehen einer Feststellschraube 6 in Kooperation mit den Vertiefungen 5 der Rasterung 4.

Wie aus den Figuren ersichtlich ist, sind die beiden Wandungen des ersten und zweiten Teiles jeweils so ausgebildet, daß

sie in Umfangsrichtung verteilt eine Vielzahl von rautenförmigen Ausnehmungen 24 aufweisen. Die einander gegenüber liegenden freien Enden 25, 26 sind, wie in den Figuren gezeigt ist, jeweils zackenförmig ausgebildet, wodurch ein drehstabilisierendes Eingreifen in die daran angrenzenden Wirbelkörperwandungen erleichtert wird. Die Ausnehmungen in der Wandung erleichtern das Einwachsen nach der Operation.

In den oben beschriebenen Ausführungsbeispielen ist die Verstelleinrichtung der Stellschraube 9, Gewindehülse 10 und Hebelarmen 7, 8 bzw. 7 jeweils so ausgebildet, daß die maximale Extension erfolgt, wenn die Gewindehülse 10 maximal zu dem Kopft 12 hinbewegt ist, und weitmöglichst zusammengeschoben, wenn die Gewindehülse 10 ihren größtmöglichen Abstand vom Kopf 12 besitzt. Es ist aber auch möglich, diese Einrichtung dahingehend umzukehren, daß die größtmögliche Extension erreicht wird, wenn die Gewindehülse 10 ihren größten Abstand vom Kopf 12 aufweist. Bei kleinstem Abstand vom Kopf 12 weist die Höhe ihren kleinstmöglichen Wert auf. Ein solches Ausführungsbeispiel ist in Figur 7 beschrieben.

Ansprüche

1. Platzhalter (1) zum Einsetzen zwischen zwei Wirbelkörper mit einer veränderbaren axialen Länge, mit einem hülsenartigen ersten Teil (2) und einem in diesem geführten und in axialer Richtung relativ zum ersten Teil (2) bewegbaren zweiten Teil (3) zum Einstellen einer Gesamtlänge, dadurch gekennzeichnet, daß die beiden Teile (2,3) durch einen Hebel (7,8) miteinander verbunden sind, dessen einer Drehpunkt (16) mit dem einen Teil (3) und dessen anderer Drehpunkt (18) wirkungsmäßig mit dem anderen Teil (2) verbunden ist.

2. Platzhalter nach Anspruch 1, dadurch gekennzeichnet, daß der Hebel (7,8) zweiarmig ausgebildet ist, wobei die beiden den Drehpunkten (16,20) abgewandten Enden mit einer auf einer in einem Langloch (11) der Wandung des ersten Teils (2) geführten Stellschraube (9) geführten Gewindehülse (10) verbunden sind.

3. Platzhalter nach Anspruch 1, dadurch gekennzeichnet, daß der andere Drehpunkt (18) mit einer auf einer in einer Bohrung (23) der Wandung des ersten Teils (2) geführten Stellschraube geführten Gewindehülse (10') verbunden ist.

4. Nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß auf der dem Loch (11, 23) gegenüber liegenden Seite die Wandung des zweiten Teiles (3) eine sich in ihrer Längsrichtung parallel zur Längsachse des Platzhalters erstreckende Längsausnehmung aufweist, in die das freie Ende der Stellschraube (9) frei hineinragt.

5. Platzhalter nach einem der Ansprüche e 1 bis 4, dadurch gekennzeichnet, daß das zweite Teil (3) auf seiner dem ersten

Teil (2) zugewandten Außenwand einen sich in axialer Richtung erstreckenden Abschnitt mit einer Rasterung (4) mit einer Mehrzahl von in axialer Richtung benachbart zueinander angeordneten und aneinandergrenzenden Vertiefungen (5) und das erste Teil (2) ein mit der Rasterung (4) zum Arretieren in einer gewünschten Länge zusammenwirkendes Feststellteil (6) aufweist.

6. Platzhalter nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Wandungen des ersten und zweiten Teiles (2,3) über die Oberfläche verteilte Ausnehmungen (24) zur Verbesserung des Einwachsen aufweisen.

Fig. 2

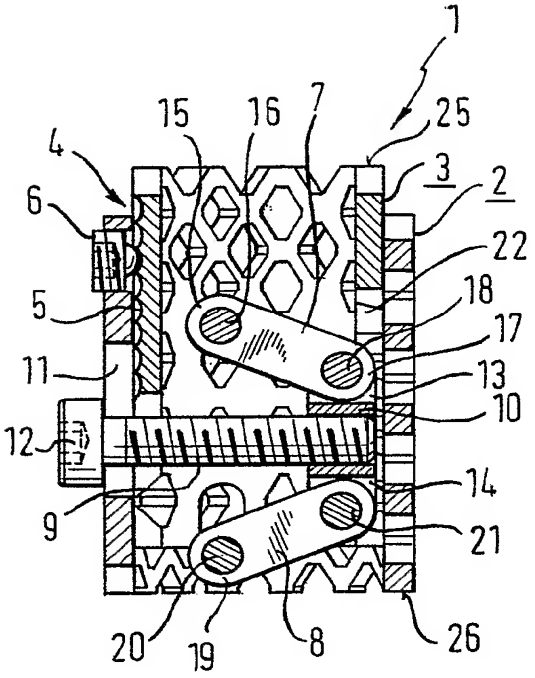


Fig. 1

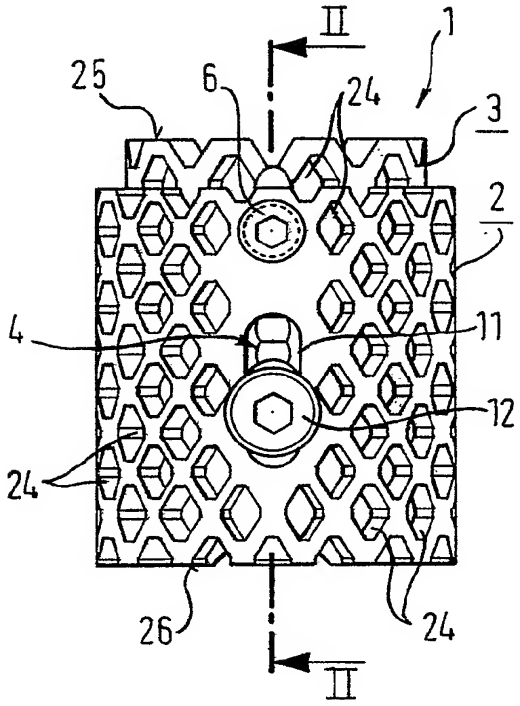


Fig. 3

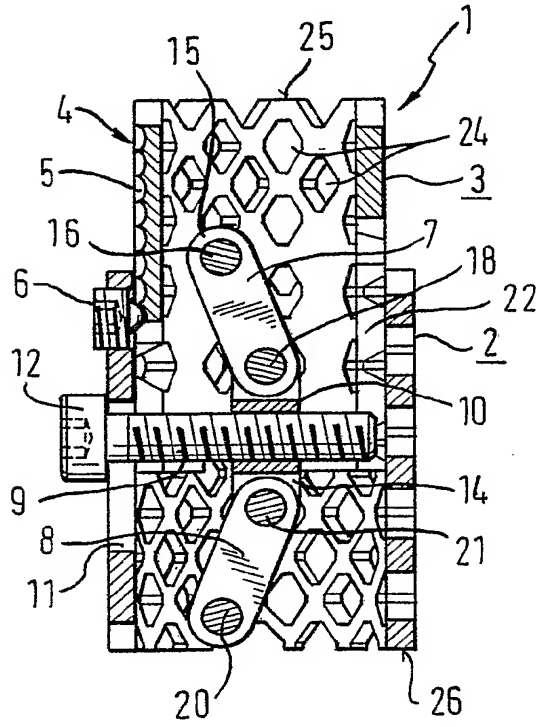


Fig. 4

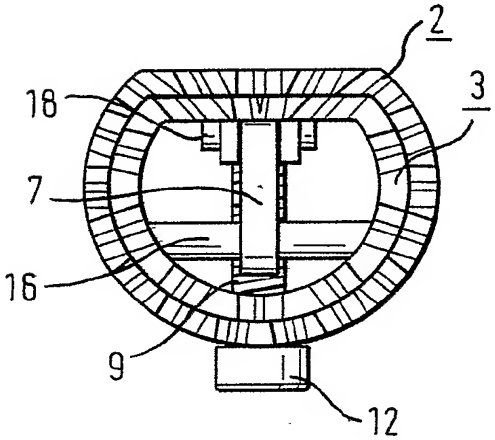


Fig. 5

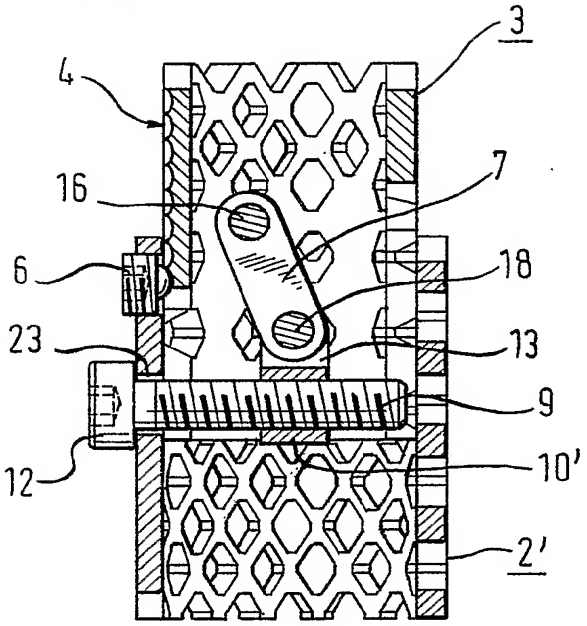


Fig. 6

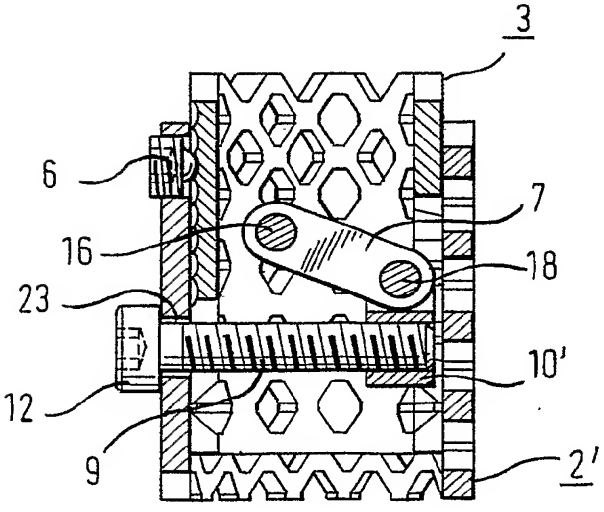
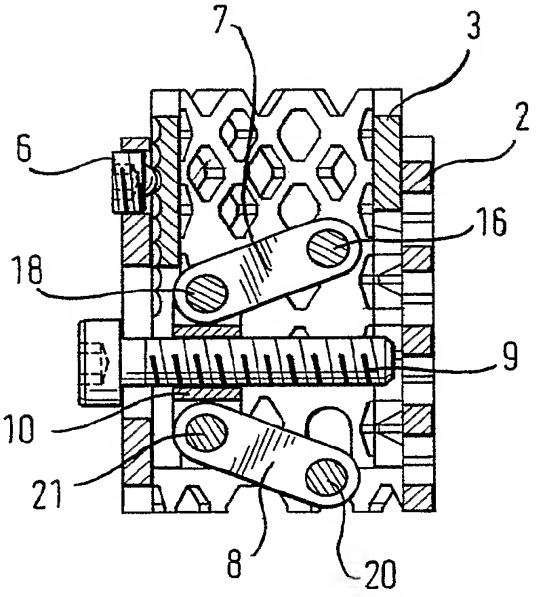


Fig. 7



INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 02/08648

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 63913 A (SURGICARFT LTD ;UPADHYAY SHANTI (GB); EVANS SAMUEL LEWIN (GB)) 16 December 1999 (1999-12-16) figure 1 siehe Zusammenfassung	1-6
A	EP 1 080 703 A (HOWMEDICA OSTEONICS CORP) 7 March 2001 (2001-03-07) figure 1	1-6
A	US 6 200 348 B1 (HARMS J UUML RGEN ET AL) 13 March 2001 (2001-03-13) cited in the application figures 5,6	1-6

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
6 November 2002	19/11/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Josten, S

INTERNATIONAL SEARCH REPORT

— information on patent family members

International Application No
PCT/EP 02/08648

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9963913 A	16-12-1999	AU 4158599 A	30-12-1999
		WO 9963913 A2	16-12-1999
EP 1080703 A	07-03-2001	AU 5350500 A	08-03-2001
		EP 1080703 A2	07-03-2001
		JP 2001104325 A	17-04-2001
US 6200348 B1	13-03-2001	DE 19804765 A1	26-08-1999
		AT 216864 T	15-05-2002
		DE 59901335 D1	06-06-2002
		WO 9939665 A1	12-08-1999
		EP 0977528 A1	09-02-2000
		JP 2002502299 T	22-01-2002

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP 02/08648

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 7 A61F2/44

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

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Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
IPK 7 A61F

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	WO 99 63913 A (SURGICARFT LTD ;UPADHYAY SHANTI (GB); EVANS SAMUEL LEWIN (GB)) 16. Dezember 1999 (1999-12-16) Abbildung 1 siehe Zusammenfassung	1-6
A	EP 1 080 703 A (HOWMEDICA OSTEONICS CORP) 7. März 2001 (2001-03-07) Abbildung 1	1-6
A	US 6 200 348 B1 (HARMS J UUML RGEN ET AL) 13. März 2001 (2001-03-13) in der Anmeldung erwähnt Abbildungen 5,6	1-6

☐ Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

☒ Siehe Anhang Patentfamilie

° Besondere Kategorien von angegebenen Veröffentlichungen :
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Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
6. November 2002	19/11/2002

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Josten, S

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Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

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Im Recherchenbericht angeführtes Patentdokument		Datum der Veröffentlichung	Mitglied(er) der Patentfamilie		Datum der Veröffentlichung
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			WO	9963913 A2	16-12-1999
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			AT	216864 T	15-05-2002
			DE	59901335 D1	06-06-2002
			WO	9939665 A1	12-08-1999
			EP	0977528 A1	09-02-2000
			JP	2002502299 T	22-01-2002